November 7, 2016

Fortress Biotech Forms New Subsidiary, Cellvation, Inc., to Develop Novel Therapies for the Treatment of Traumatic Brain Injury

Cellvation to Advance Three Programs Licensed from UTHealth

Two Phase 2 Studies Supported by Approximately $10M in Secured Grant Funding

Frank Taffy to Serve as Interim Chief Executive Officer

NEW YORK, Nov. 07, 2016 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc., (NASDAQ:FBIO) has formed a new subsidiary company, Cellvation, Inc., to develop novel therapies for the treatment of traumatic brain injury ("TBI"). Cellvation has entered into an agreement with The University of Texas Health Science Center at Houston (UTHealth) to secure exclusive worldwide rights to three programs for TBI, including two Phase 2 cell therapies.

For the pediatric population, a randomized, multi-center, double-blind, placebo-controlled, Phase 2 study of autologous bone marrow-derived stem cells for the treatment of severe TBI is ongoing and will enroll up to 50 patients (ClinicalTrials.gov Identifier: NCT01851083). For adults, a soon-to-be-commenced, randomized, double-blind, placebo-controlled, Phase 2 study of autologous bone marrow-derived stem cells for the treatment of severe TBI will enroll up to 55 patients (ClinicalTrials.gov Identifier: NCT02525432). The Phase 2 studies are supported by secured grants of approximately $10 million from the National Institutes of Health and the Department of Defense. Cellvation plans to strategically supplement this grant funding to open additional clinical sites and accelerate study outcomes.

According to the Centers for Disease Control and Prevention, TBI is a leading cause of death and disability in adults and children in the United States, contributing to almost one third of all injury-related mortalities. TBI results from a trauma or jolt to the head (or a penetrating head injury) that impacts normal brain function. TBIs range in severity from "mild" (a brief change in mental status or consciousness, often referred to as a concussion) to "severe" (an extended period of unconsciousness typically requiring hospitalization). Based on the National Hospital Discharge Survey, there were approximately 2.5 million TBIs in the United States in 2010, which resulted in more than 50,000 deaths and 280,000 hospitalizations. Injuries associated with TBI cost an estimated $76 billion annually in the United States.

Cellvation also licensed rights from UTHealth to a next-generation bioreactor that enhances the anti-inflammatory potency of bone marrow-derived cells without genetic manipulation. As Cellvation continues clinical development of its lead programs in the United States, it will explore early market entry in Japan under the recently revised Pharmaceutical Affairs Law, which provides for conditional approval of regenerative medicine products upon demonstration of safety and efficacy in early clinical studies.

The Cellvation programs were developed by Dr. Charles Cox, George & Cynthia Mitchell Distinguished Chair in Neurosciences; Director, Children's Regenerative Medicine, McGovern Medical School at the UTHealth Department of Pediatric Surgery; and Co-Director of the Memorial Hermann Red Duke Trauma Institute. Dr. Cox will serve as a key scientific advisor to the Company. "Cellular therapies are a highly promising strategy to mitigate the neuroinflammatory response to TBI that amplifies the initial injury," said Dr. Cox. "Targeting this 'secondary brain injury' is designed to preserve injured tissue and ultimately improve outcomes. We are excited to work with the Cellvation team to advance these important programs."

Dr. Lindsay A. Rosenwald, Chairman and CEO of Fortress Biotech, stated, "We are pleased to enter into this collaboration with UTHealth and Dr. Charles Cox. TBI is associated with significant unmet medical need and a standard of care that hasn't evolved much over the past two decades. Data generated by Dr. Cox and his team suggest a cell therapy could reduce further injury following a head trauma and improve long-term outcomes. We look forward to continuing development of these exciting therapies and delivering them to the bedside."

Fortress also announced the appointment of Frank Taffy as interim Chief Executive Officer, President and member of Cellvation's Board of Directors. Mr. Taffy identified the Cellvation programs and co-founded the company. He has more than 15 years of experience in life sciences corporate development and operations. Mr. Taffy currently serves as President, Chief Executive Officer and member of the Board of Directors for Helocyte, Inc., a company he also co-founded that is focused on the development of novel immunotherapies for cancer and infectious disease. He previously held the positons of Head (Senior Director) of Business Affairs at Forest Laboratories (now Allergan) and Director of Corporate Development at Life Technologies (now Thermo Fisher Scientific), where he also held Board positions on behalf of the company. Mr. Taffy began his career as Counsel for Intellectual Property at Procter & Gamble. He holds a J.D. from Syracuse University College of Law and a B.A. in biochemistry from the University of North Texas.

About Bone Marrow-Derived Stem Cells for the Treatment of Traumatic Brain Injury
Traumatic brain injury ("TBI") remains one of the greatest unsolved problems in clinical trauma care today. Cell-based therapy is distinguished from small molecule strategies by the pleiotropic mechanisms of action that have been determined in preclinical data and an excellent safety profile in early clinical trials. Proof of concept data have been developed using bone marrow mononuclear cells in both stroke and TBI, and these data formed the foundation for translation into Phase 1 and 2 clinical trials at UTHealth. The mechanism of action appears to be related to down-regulation of neuroinflammatory response of the innate immune system. Cellvation further licensed rights from UTHealth to a novel bioreactor that amplifies anti-inflammatory gene programs in adherent bone marrow derived mesenchymal stromal cells without external gene transfection approaches. The utility of this approach has

been confirmed using *in vivo* models of TBI. Development of this pipeline of cellular therapeutics represents an opportunity to fundamentally change the approach to TBI treatment.

About The University of Texas Health Science Center at Houston
Established in 1972 by The University of Texas System Board of Regents, The University of Texas Health Science Center at Houston (UTHealth) is Houston's Health University and Texas' resource for health care education, innovation, scientific discovery and excellence in patient care. The most comprehensive academic health center in The UT System and the U.S. Gulf Coast region, UTHealth is home to schools of biomedical informatics, biomedical sciences, dentistry, nursing and public health and the John P. and Kathrine G. McGovern Medical School. UTHealth includes The University of Texas Harris County Psychiatric Center and a growing network of clinics throughout the region. The university's primary teaching hospitals include Memorial Hermann-Texas Medical Center, Children's Memorial Hermann Hospital and Harris Health Lyndon B. Johnson Hospital. For more information, visit www.uth.edu.

UTHealth is a leader in cell therapeutics for neurological injury and has developed novel approaches to the treatment of traumatic brain injury. McGovern Medical School at UTHealth is a collaborator with Memorial Hermann-Texas Medical Center in the Memorial Hermann Red Duke Trauma Institute and Memorial Hermann Mischer Neuroscience Institute. Memorial Hermann-TMC is one of the busiest Level 1 American College of Surgeons-verified Adult and Pediatric Trauma Centers in the country.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes its products both within Fortress and through subsidiary companies, also known as Fortress Companies, and also develops other products relating to financial services through its affiliate, National Holdings Corporation (NASDAQ:NHLD). In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensing, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. 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. 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 related to our growth strategy; risks relating to the results of research and development activities; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; our dependence on third party suppliers; 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.

Contacts:

Cellvation, Inc.
Frank Taffy, Co-Founder, Interim CEO, President, Board Member
(212) 554-4520
frank@helocyte.com

Fortress Biotech, Inc.
Lucy Lu, MD, Executive Vice President & Chief Financial Officer
(781) 652-4500
ir@fortressbiotech.com

Fortress Biotech Media Relations
Laura Bagby
6 Degrees
(312) 448-8098
lbagby@6degreespr.com

UTHealth Media Relations
Charles Cox, M.D.
Via Deborah Mann Lake
(713) 500-3030
Deborah.m.lake@uth.tmc.edu

Source: Fortress Biotech, Inc.