



DATA FROM CLINICAL STUDY OF CELL THERAPY FOR TREATMENT OF TRAUMATIC BRAIN INJURY PUBLISHED IN *STEM CELLS*

Cell therapy safe, effective in mitigating neuroinflammatory response and preserving brain tissue after TBI

Positive Phase 1 data support ongoing Phase 2 trials in pediatric and adult patients

NEW YORK, NY – November 17, 2016 – Cellvation, Inc., a clinical-stage biopharmaceutical company and majority-owned subsidiary of Fortress Biotech, Inc. (NASDAQ: FBIO) developing novel cell therapies for the treatment of traumatic brain injury ("TBI"), announced today data demonstrating a patient's own stem cells may be safe and effective in diminishing neuroinflammatory response and preserving brain tissue in adults following severe TBI. Data from a Phase 1 study of Cellvation's CEVA101, an autologous bone marrow-derived mononuclear cell therapy, were published online this month in the journal [STEM CELLS](#).

Researchers at The University of Texas Health Science Center at Houston (UTHealth) conducted the dose-escalation study in 25 adults with severe TBI and without signs of irreversible brain injury. Bone marrow harvest, cell processing and re-infusion occurred within 48 hours after injury. The bone marrow mononuclear cells were observed to be safe and well-tolerated, with no serious adverse events related to the harvest or infusion. Furthermore, investigators in the study found evidence of central nervous system structural preservation, consistent with data from a Phase 1 pediatric trial of Cellvation's CEVA101, and the mitigation of inflammatory biomarkers following cell infusion.

"The data derived from this trial moves beyond just testing safety of this approach," said Charles S. Cox, Jr., M.D., principal investigator, the George and Cynthia Mitchell Distinguished Chair in Neurosciences at UTHealth, professor in the Department of Pediatric Surgery and co-director of the Memorial Hermann Red Duke Trauma Institute. "We now have a hint of a treatment effect that mirrors our pre-clinical work, and we are now pursuing this approach in a Phase 2b clinical trial sponsored by the Joint Warfighter Program within the U.S. Army Medical Research Acquisition Activity, as well as our ongoing Phase 2b pediatric severe TBI clinical trial – both using the same autologous cell therapy."

The Phase 1 study was supported by U.S. Department of Defense grant W81XWH-11-1-0460, National Institutes of Health grant 2T32 GM 0879201-11, the Glassell Foundation Stem Cell Research Program and The Brown Foundation, Inc.

"To our knowledge, the *STEM CELLS* publication is the first reported clinical assessment of an IV-infused cell therapy for the treatment of severe TBI in adults. The data set is compelling and suggests that CEVA101 could be a safe and effective approach in the acute trauma setting," said Frank Taffy, co-founder, interim CEO, President and a member of Cellvation's Board of Directors. "We are thrilled to be working with UTHealth to advance this innovative program in a high-risk setting characterized by significant unmet medical need."

Charles S. Cox, Jr., M.D., and UTHealth have research-related financial interests in Fortress, including its subsidiary Cellvation.

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. The mechanism of action appears to be related to down-regulation of neuroinflammatory response of the innate immune system. Proof of concept data have been generated by The University of Texas Health Science Center at Houston (UTHealth) using bone marrow mononuclear cells (BMMNCs) in both stroke and TBI. These data formed the foundation for Phase 1 and 2 clinical trials of Cellvation’s BMMNCs (CEVA101) in pediatric patients with severe TB and in adults with severe TBI. Cellvation also maintains rights to CEVA-D, 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 Cellvation

Cellvation, Inc., is a clinical-stage biopharmaceutical company developing novel cellular therapeutics for the treatment of traumatic brain injury (“TBI”). Cellvation is currently advancing clinical-stage cell therapies in severe TBI: a Phase 2 study of CEVA101 in pediatric patients ([ClinicalTrials.gov Identifier: NCT01851083](#)), and a Phase 2 study of CEVA101 in adults ([ClinicalTrials.gov Identifier: NCT02525432](#)). These studies are supported by grants of approximately \$10 million from the National Institutes of Health and the Department of Defense. Cellvation is also developing CEVA-D, a novel bioreactor that enhances the anti-inflammatory potency of bone marrow-derived cells without genetic manipulation. Cellvation is a majority-owned subsidiary of Fortress Biotech (NASDAQ: FBIO) and is based in New York City.

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 products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. Additionally, Fortress recently acquired a controlling interest in National Holdings Corporation (NASDAQ: NHLD), a diversified independent brokerage company (together with its subsidiaries, “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 licensings, 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.

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