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Fortress Biotech Announces Cellvation's CEVA101 Granted FDA Regenerative Medicine Advanced Therapy Designation for the Treatment of Traumatic Brain Injury

Designation to facilitate expedited development and review of CEVA101 for TBI

CEVA101 is being developed in partnership with The University of Texas Health Science Center at Houston (UTHealth)

NEW YORK, Nov. 08, 2017 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ:FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced that the U.S. Food and Drug Administration (FDA) has granted Cellvation's CEVA101 (autologous bone marrow-derived stem cells) Regenerative Medicine Advanced Therapy ("RMAT") designation for the treatment of traumatic brain injury ("TBI"). Under terms of the RMAT designation, the FDA will help facilitate the program's expedited development and review, and will provide guidance on generating the evidence needed to support approval of CEVA101 for TBI. CEVA101 is currently being assessed in Phase 2 clinical trials for severe TBI in children (ClinicalTrials.gov Identifier: NCT01851083) and adults (ClinicalTrials.gov Identifier: NCT02525432).

“The FDA's grant of RMAT designation for CEVA101 further validates the compelling safety and efficacy data generated to date, and affirms the program's potential to address a serious and life-threatening condition," said Frank Taffy, Co-Founder, CEO, President & Board Member of Cellvation. Mr. Taffy continued, “We will continue to work closely with the FDA and our partners at UTHealth to drive the development of this critically-needed treatment option."

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, said, “The RMAT designation represents a positive, rigorous review of our entire portfolio of translational and clinical stage work on CEVA101 for severe traumatic brain injury. Most importantly, it is a recognition that CEVA101 is a potential breakthrough to treat severe TBI.”

The RMAT designation makes a regenerative medicine advanced therapy product eligible for the same actions to expedite the development and review of a marketing application that are available to drugs that receive Breakthrough Therapy Designation, including timely advice and interactive communications with FDA, as well as proactive and collaborative involvement by senior FDA managers and experienced review and regulatory health project management staff. A product designated as an RMAT also may be eligible for other FDA-expedited programs, such as Priority Review. The FDA also may conduct a rolling review of products in its expedited programs, reviewing portions of a marketing application before the complete application is submitted.

The FDA’s RMAT designation is a primary component of the 21st Century Cures Act, signed into law in December 2016. According to this legislation, eligible drugs include regenerative medicine therapy, further defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination product using such therapies or products. Further, eligible drugs are those intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and present preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for such disease or condition. The FDA has determined that CEVA101 for the treatment of TBI with Glasgow Coma Score between 3 and 8 meets the criteria for RMAT designation.

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. UTHealth is also a leader in cellular 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 (Memorial Hermann-TMC) 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. For more information, visit www.uth.edu.

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 including: a Phase 2 study of CEVA101 in children (ClinicalTrials.gov Identifier: NCT01851083), and a Phase 2 study of CEVA101 in adults (ClinicalTrials.gov Identifier: NCT02525432). These studies are supported by grants in excess of $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 subsidiary companies, also known as Fortress Companies. 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 arrangements, 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, as amended. 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 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; 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 required by law.

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