June 19, 2018

Fortress Biotech Announces Publication of Phase 1 Data on CNDO-109-Activated Allogeneic Natural Killer Cells in Acute Myeloid Leukemia in Biology of Blood and Marrow Transplantation

Data demonstrate CNDO-109-activated NK cells are safe, well tolerated and capable of extending complete remissions in high-risk acute myeloid leukemia patients

NEW YORK, June 19, 2018 (GLOBE NEWSWIRE) -- Fortress Biotech (NASDAQ:FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced that data from a Phase 1 clinical trial evaluating Fortress' CNDO-109-activated allogeneic natural killer (NK) cells in acute myeloid leukemia (AML) patients have been published in the journal *Biology of Blood and Marrow Transplantation*.

Todd A. Fehniger, M.D., Ph.D., Associate Professor of Medicine, Oncology Division at Washington University School of Medicine, and lead investigator on the Phase 1 trial, said, "This is an important early phase, dose-escalation trial that clearly identified the safety and feasibility of the innovative approach to prime donor NK cells with tumor cell lysates prior to adoptive transfer. The very durable responses that were achieved in several of the AML patients consolidated with CNDO-109-NK are exciting, and warrant further study in a larger number of patients."

The multi-center, non-randomized, open-label, dose-escalation Phase 1 trial evaluated the maximum tolerated dose of CNDO-109-activated NK cells in 12 adult AML patients in their first complete remission who were at a high risk of relapsing. Evaluation of the safety profile, the duration of relapse-free survival and overall survival were secondary objectives.

CNDO-109-activated NK cells were prepared from a single leukapheresis product of peripheral blood mononuclear cells from a healthy, HLA-haploidentical first or second-degree relative. The NK (CD56+) cells were purified and incubated *ex vivo* with CNDO-109 lysate. Cytokines were not used in the incubation process.

CNDO-109-activated NK cells were well tolerated, with no infusion-related adverse events or

graft-versus-host disease reported. Three patients had long-term, relapse-free survivals of 32.6, 42.5+ and 47.6+ months after treatment, with two patients remaining relapse-free at the time of publication.

Lindsay A. Rosenwald, M.D., Fortress' Chairman, President and Chief Executive Officer, said, "We are encouraged by the early safety and efficacy profile demonstrated by CNDO-109-activated NK cells in AML patients, and look forward to continuing to advance the program."

The publication can be accessed on the *Biology of Blood and Marrow Transplantation* website at https://www.bbmt.org/article/S1083-8791(18)30132-0/fulltext.

CNDO-109-Activated Allogeneic Natural Killer Cells
CNDO-109 is a lysate (disrupted CTV-1 cells, cell membrane fragments, cell proteins and other cellular components) that activates donor natural killer (NK) cells *ex vivo*. Fortress acquired exclusive worldwide development and commercialization rights to CNDO-109-activated NK cells for the treatment of cancer from the University College London Business.

About Acute Myeloid Leukemia
Acute myeloid leukemia (AML) is one of the deadliest and most common types of acute leukemia in adults. According to a Decision Resources Group report, there are more than 43,000 cases worldwide, primarily afflicting elderly and relapsed and refractory populations. Once diagnosed with AML, patients typically receive induction and consolidation chemotherapy, with the majority achieving complete remission. However, roughly 70–80 percent of patients who achieve first complete remission will relapse, and the overall five-year survival rate is less than 25 percent.

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 may be required by law.

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Source: Fortress Biotech, Inc.