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Fortress Biotech Announces Positive Clinical Data From Fortress Companies Presented at the 59th American Society of Hematology Annual Meeting

Columbia University reports Caelum Biosciences' CAEL-101 was well tolerated, demonstrated early and clinically efficacious organ response in Phase 1a/1b trial in AL amyloidosis

City of Hope announces Mustang Bio's MB-102 (CD123 CAR) achieves first-reported complete response from a CAR T therapy in a BPDCN patient, additional complete response attained in AML in Phase 1 trial

Data were presented in oral sessions at ASH

NEW YORK, Dec. 11, 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 positive clinical data on therapies under development at its Fortress Company subsidiaries Caelum Biosciences, Inc. ("Caelum"), and Mustang Bio, Inc. ("Mustang") (NASDAQ:MBIO), were presented in oral sessions at the 59th American Society of Hematology (ASH) Annual Meeting.

Dr. Lindsay A. Rosenwald, Fortress Biotech's Chairman, President and Chief Executive Officer, said, "We are delighted to report that data from two of our Fortress Companies were presented in oral sessions at ASH, which is a testament to our top-notch business development engine's expertise in securing compelling assets and our corporate strategy of partnering with first-rate academic and commercial entities."

Dr. Rosenwald added, "Trial investigators at Columbia concluded that Caelum's CAEL-101 dosed once weekly demonstrated early and clinically efficacious organ responses throughout a Phase 1a/1b trial, underscoring its potential to be a best-in-class treatment in AL amyloidosis and providing signals to support advancement into a Phase 2b/3 trial in the second half of 2018. In addition, trial investigators at City of Hope found that Mustang Bio's MB-102 CAR T therapy was safe, well tolerated and achieved a complete response in acute myeloid leukemia and blastic plasmacytoid dendritic cell neoplasm in an ongoing Phase 1 trial. According to City of Hope, this is the first BPDCN patient to achieve a complete

response to a CAR T cell therapy."

Caelum's CAEL-101 improves organ function in AL amyloidosis

Twenty-seven patients were treated with CAEL-101 in this open-label, dose-escalation trial. In the Phase 1a trial, CAEL-101 was administered to eight patients via a single IV infusion at week one. In the Phase 1b trial, CAEL-101 was administered to 19 patients via one weekly IV infusion for four weeks. Trial investigators at Columbia University ("Columbia") determined the study achieved its primary objective of establishing maximum tolerated dose of up to 500mg/m^2 of CAEL-101.

Trial investigators presented organ response rates in the Phase 1a and the Phase 1b, with 63 percent (14 of 24) overall organ response rate, 67 percent (8 of 12) overall cardiac response rate and 50 percent (5 of 10) overall renal response rate.[1] Early organ response was demonstrated in a high-mortality population (21 days median time to cardiac response in Phase 1b; 28 days median time to renal response in Phase 1b[2]).

Trial investigators found that CAEL-101 achieved and demonstrated organ response at multiple points in time throughout the duration of treatment; all patients showed an organ response or were stable, and no patients showed organ progression. Organ response independent of a chemotherapy-free light chain response was demonstrated. No drug-related grade 4 or 5 adverse events or dose-limiting toxicities were seen in the trial. There was no mortality during the study. The investigators followed patients beyond the study and reported an overall survival rate of 93 percent (median follow-up period of 18.6 months).

A copy of the presentation can be viewed online on the Publications page of the Caelum website at www.caelumbio.com/pipeline/publications.

Mustang's MB-102 (CD123 CAR) CAR T therapy achieves complete response in AML and BPDCN

This ongoing, single center, first-in-human Phase 1 dose-escalation clinical trial (NCT02159495) at City of Hope is evaluating the safety and activity of escalating doses of MB-102 in patients with relapsed or refractory acute myeloid leukemia (AML) (cohort 1) and blastic plasmacytoid dendritic cell neoplasm (BPDCN) (cohort 2). Patients receive a single dose of MB-102 with an option for a second infusion if they continue to meet safety and eligibility criteria and still have CD123+ disease. To date, 14 patients have been enrolled and seven have been treated (six with AML, one with BPDCN) in this first in-human trial for AML and BPDCN patients using a CD123 CAR T therapy.

In the AML cohort, two patients were treated at dose level 1 (50M CAR+ T). Trial investigators reported that one achieved a morphologic leukemic-free state at day 28 post-infusion. Four patients received dose level 2 (200M CAR+ T), with a complete response (CR) observed at day 28 in one patient, and a CR with incomplete blood count recovery demonstrated at day 28 in a second patient. Both patients proceeded to a second allogeneic hematopoietic stem cell transplantation.

In the BPDCN cohort, one patient received a single dose of 100M CAR+ T and achieved a CR at day 28, which lasted at least 60 days, according to investigators. Of note, this patient had previously experienced disease progression following five cycles of treatment with a

CD123-targeted recombinant fusion protein.

Investigators found MB-102 infusions of up to 200M CAR T cells were safe, with no graft-versus-host disease, myeloablative effects, neurologic toxicity or dose-limiting toxicities. Adverse events (AEs) included: cytokine release syndrome (six grade 1, one grade 2), neurotoxicity (dizziness: one grade 1, two grade 2; headache (five grade 1, two grade 2); somnolence (one grade 1, two grade 2), three cases of infection (lung infection: two, other: one). The most common ≥ grade 3 AEs included lymphopenia (seven), thrombocytopenia (seven) and febrile neutropenia (six).

About Caelum Biosciences
Caelum Biosciences, Inc. ("Caelum"), a Fortress Biotech (NASDAQ:FBIO) Company, is a clinical-stage biotechnology company developing treatments for rare and life-threatening diseases. Caelum's lead asset, CAEL-101 (mAb 11-1F4), is a novel antibody for the treatment of patients with amyloid light chain ("AL") amyloidosis. Phase 1a/1b data presented at the American Society of Hematology's 59th Annual Meeting in December 2017 support CAEL-101's potential to be a safe and well-tolerated therapy that promotes amyloid resolution. CAEL-101 has received Orphan Drug Designation from the U.S. Food and Drug Administration as a therapeutic agent for patients with AL amyloidosis, and as a radio-imaging agent in amyloidosis. For more information, visit www.caelumbio.com.

About Mustang Bio
Mustang Bio, Inc., a subsidiary of Fortress Biotech, Inc., is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel cancer immunotherapy products designed to leverage the patient's own immune system to eliminate cancer cells. Mustang aims to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding research and development, and outlicensing or bringing the technologies to market. Mustang has partnered with the City of Hope National Medical Center ("COH") and the Fred Hutchinson Cancer Research Center in the development of proprietary chimeric antigen receptor ("CAR") engineered T cell ("CAR T") therapies across many cancers, and with Harvard Medical School's Beth Israel Deaconess Medical Center and the Harvard Stem Cell Institute for the development of CRISPR/Cas9-enhanced CAR T therapies in hematologic malignancies and solid tumors. Mustang's lead programs are in Phase 1 clinical trials at COH: MB-101 for the treatment of brain cancer and MB-102 as a therapeutic agent in acute myeloid leukemia and blastic plasmacytoid dendritic cell neoplasm. Mustang is registered under the Securities Exchange Act of 1934, as amended, and files periodic reports with the U.S. Securities and Exchange Commission. For more information, visit www.mustangbio.com.

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, each 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 value. 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; risks relating to the timing of starting and completing clinical trials; 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 required by law.

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[1] Response rates are based on the number of evaluable patients.

[2] First renal response evaluation point was 28 days for all but one patient, who was evaluated at 21 days.

Source: Fortress Biotech, Inc.