Caelum Biosciences Announces Complete Cardiac Data Analysis from Phase 1b Trial of CAEL-101 in AL Amyloidosis

Nine of 10 cardiac patients on CAEL-101 showed improvement in global longitudinal strain

CAEL-101 led to sustained decrease in NT-proBNP levels

Data presented at American Society of Echocardiography 29th Annual Scientific Sessions

NEW YORK, NY – June 25, 2018 – Caelum Biosciences, Inc. ("Caelum"), a Fortress Biotech, Inc. (NASDAQ: FBIO) Company developing treatments for rare and life-threatening diseases, today announced a complete analysis of cardiac data from Columbia University's ("Columbia") Phase 1b trial that supports CAEL-101's (mAb 11-1F4) potential to improve myocardial function as assessed by global longitudinal strain ("GLS") and generate a sustained decrease in N-terminal pro-brain natriuretic peptide (NT-proBNP) levels in amyloid light chain ("AL") amyloidosis patients experiencing cardiac involvement. These data were presented at the American Society of Echocardiography (ASE) 29th Annual Scientific Sessions.

"Cardiac involvement can indicate a poor prognosis in patients with AL amyloidosis, and is the cause of more than 75 percent of one-year mortality," said Sofia Shames, M.D., Assistant Professor at Columbia University Medical Center and investigator on the Phase 1b trial. "The Phase 1b trial of CAEL-101 is the first clinical study to show a significant improvement in GLS after exposure to an anti-fibril specific mAb in people with AL amyloid cardiac involvement. This is important, as echocardiographical GLS may be more effective in predicting overall and cardiovascular mortality than traditional ejection fraction, which warrants further evaluation in clinical trials."

Myocardial response was assessed using GLS as part of a long-term analysis of data from the Phase 1b trial. GLS is a measure of myocardial shortening during systole, which may detect early cardiac functional improvement and be a predictor of cardiac survival.

Nineteen patients with relapsed or refractory AL amyloidosis enrolled in the Phase 1b trial had a baseline echocardiogram taken at their initial screening visit. Ten of 19 patients (52 percent) had cardiac involvement at the time of their baseline echocardiogram reading as defined by NT-proBNP levels (>650 pg/ml), an important biomarker in cardiac disease. CAEL-101 was administered weekly for four weeks in the multi-ascending dose trial. The dose escalation included the doses 0.5, 5, 10, 50, 100, 250 and 500 mg/m^2. Clinical echocardiographic examinations at baseline and 12 weeks post therapy were compared.

Patients with cardiac involvement demonstrated an improvement in GLS (-15.58 $\pm$ -4.14 percent pre-treatment / -17.37 $\pm$ -3.53 percent post-treatment, p=0.004). Patients with both kappa and lambda amyloid light chain subtypes were studied. The change in GLS patients with a p-value of 0.004 and the lack of response in patients without cardiac involvement supports further clinical development in patients with cardiac AL amyloidosis.

In addition, mean NT-proBNP reduction was presented, which demonstrated that there was an improvement in NT-proBNP in eight evaluable patients with cardiac amyloid involvement after four

weekly doses. The NT-proBNP patient response criteria were a 30-percent reduction and a 300 pg/ml reduction from baseline.

The full abstract was published in the June 2018 edition of the *Journal of the American Society of Echocardiography*.

About AL Amyloidosis
AL amyloidosis is a rare systemic disorder caused by an abnormality of plasma cells in the bone marrow. Misfolded amyloid proteins produced by plasma cells cause buildup in and around tissues, nerves and organs, gradually affecting their function. This can cause progressive and widespread organ damage, and high mortality rates.

AL amyloidosis affects roughly 30,000 – 40,000 patients in total throughout the U.S. and Europe, and it is estimated that there are approximately 3,000 – 4,000 new cases of AL amyloidosis annually in the U.S., though actual incidence is likely higher as a result of under-diagnosis. Amyloidosis has a one-year mortality rate of 47 percent, 76 percent of which is caused by cardiac amyloidosis.

About CAEL-101 (mAb 11-1F4)
CAEL-101 is a chimeric fibril-reactive monoclonal antibody (mAb) that has completed a Phase 1a/1b trial at Columbia University for the treatment of patients with relapsed or refractory AL amyloidosis. While current treatment with chemotherapy is aimed at reducing production of the amyloid-forming light-chain protein, CAEL-101 attempts to reduce and / or eliminate the amyloid deposits.

About the Phase 1a/1b trial
The Phase 1a/1b trial (ClinicalTrials.gov Identifier: NCT02245867) examined the tolerance, safety, pharmacokinetics and possible clinical benefit of CAEL-101 (mAb 11-1F4) in patients with relapsed or refractory AL amyloidosis. CAEL-101 was administered weekly for four weeks with sequential doses of 0.5, 5, 10, 50, 100, 250 and 500 mg/m^2. CAEL-101 was administered to eight patients via a single IV infusion at week one in the Phase 1a portion of the trial, and to 19 patients via one weekly IV infusion for four weeks in the Phase 1b portion of the trial.

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 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 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, 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.

Contacts:

Caelum Biosciences, Inc.
Michael Spector, President & Chief Executive Officer
(212) 574-2811
mspector@caelumbio.com

Fortress Biotech, Inc.
Jaclyn Jaffe, Investor Relations
(781) 652-4500
ir@fortressbiotech.com

Fortress Biotech, Inc.
Tony Plohoros, Media Relations
6 Degrees
(908) 591-2839
tplohoros@6degreesPR.com