



FORTRESS BIOTECH ANNOUNCES FINAL PATIENT DOSED IN PHASE 1B TRIAL OF CAEL-101 FOR THE TREATMENT OF AL AMYLOIDOSIS

CAEL-101 is in development by Fortress subsidiary Caelum Biosciences

Preliminary Phase 1b data expected mid-2017; full data readout anticipated in late 2017

Phase 2 study planned for the first half of 2018

NEW YORK, NY – May 4, 2017 – Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced that study sponsor Columbia University (“Columbia”) has dosed the final patient in the Phase 1b clinical trial of CAEL-101, in development by Fortress subsidiary Caelum Biosciences, Inc. (“Caelum”) for the treatment of amyloid light chain (“AL”) amyloidosis. Caelum expects to readout preliminary Phase 1b data mid-2017, and full data by the end of the year.

Michael Spector, Chief Executive Officer of Caelum, said, “The dosing of the final patient in our Phase 1 program is a key milestone for Caelum. CAEL-101 has the potential to provide an improved treatment option for people suffering from AL amyloidosis, a rare and fatal disease that lacks adequate therapeutic options. We look forward to presenting trial data later this year, and to initiating a Phase 2 study in the first half of 2018.”

The Phase 1a/1b study (ClinicalTrials.gov Identifier: [NCT02245867](https://clinicaltrials.gov/ct2/show/study/NCT02245867)) is examining the tolerance, safety, pharmacokinetics and possible clinical benefit of CAEL-101, a chimeric fibril-reactive monoclonal antibody (mAb), in patients with AL amyloidosis. CAEL-101 was administered to patients through a single intravenous infusion in the Phase 1a, and one weekly infusion for four weeks during the Phase 1b. The first patient received the starting dose and, if tolerated, the following patients received progressively higher doses. When trial investigators reached the maximum tolerated dose without toxicity, investigators enrolled another six patients to receive the same dose.

Interim Phase 1a/1b data presented by Columbia at the American Society of Hematology’s (ASH) 58th Annual Meeting demonstrated that CAEL-101 is safe and well-tolerated with no drug-related adverse events or dose-limiting toxicity up to 500mg/m². A single infusion of CAEL-101, or one weekly infusion for four weeks, provided early and sustained organ response in cardiac, renal, gastrointestinal, skin and soft tissue. Interim clinical efficacy data showed that CAEL-101 promoted amyloid resolution in 67 percent of patients (63 percent in Phase 1a; 70 percent in Phase 1b).

Suzanne Lentzsch, M.D., Ph.D., Professor of Medicine at Columbia University Medical Center, College of Physicians and Surgeons of Columbia University and at New York Presbyterian Hospital, and principal investigator for the Phase 1a/1b study, said, “Standard-of-care chemotherapy is directed toward

eliminating plasma cells that produce abnormal proteins, but does not adequately address new and existing amyloid build-up in organs, which can lead to organ failure and even death. CAEL-101 is specifically designed to bind to misfolded proteins and promote resolution. We look forward to translating the compelling biomarker results seen in the Phase 1a/1b to-date, in which CAEL-101 demonstrated sustained organ response after a single dose, into further clinical benefit and positive patient outcomes.”

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.

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 (11-14F), is a novel antibody in Phase 1b clinical trials for the treatment of patients with amyloid light chain (“AL”) amyloidosis. Interim Phase 1a/1b data presented at the American Society of Hematology’s 58th Annual Meeting in December 2016 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; 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 ability to obtain, perform under and maintain financing and strategic agreements and relationships; 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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