



FORTRESS BIOTECH FORMS NEW SUBSIDIARY, CAELUM BIOSCIENCES, INC., TO DEVELOP NOVEL TREATMENT FOR AL AMYLOIDOSIS

Caelum Program Evaluating CAEL-101 (11-1F4) for AL Amyloidosis In-licensed from Columbia University

Data from ongoing Phase 1a/1b study of CAEL-101 presented by Dr. Suzanne Lentzsch at ASH have demonstrated CAEL-101 is safe and well tolerated; 67 percent of patients showed improvement in organ function

Michael Spector to Serve as Chief Executive Officer

NEW YORK, NY – January 4, 2017 – Fortress Biotech, Inc. (Nasdaq: FBIO) today announced the formation of a new subsidiary company, Caelum Biosciences, Inc., to advance the development of CAEL-101 (11-1F4) for the treatment of amyloid light chain (“AL”) amyloidosis. Caelum has entered into an agreement with Columbia University (“Columbia”) to secure exclusive worldwide license rights to CAEL-101, a chimeric fibril-reactive monoclonal antibody (mAb) currently being evaluated in a Phase 1a/1b study. In addition, Fortress announced the appointment of Michael Spector as Caelum’s Chief Executive Officer.

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.

Alan Solomon, M.D., Professor of Medicine Emeritus and a former American Cancer Society Clinical Research Professor at the University of Tennessee Graduate School of Medicine, who pioneered early development of antibodies that work to break up pre-existing amyloid in tissues and oversaw preclinical research on CAEL-101, said: “Existing AL amyloidosis treatment using chemotherapy eliminates the plasma cells that produce the abnormal proteins, but most often the pathologic amyloid deposits in the body’s vital tissues remain or progress, resulting in organ failure and even death. For this reason, our research efforts were focused on helping the body’s immune system remove this deleterious material. Our “anti-amyloid” monoclonal antibody 11-1F4, now designated CAEL-101, has demonstrated its ability to bind to amyloid and promote dissolution in mice bearing human AL amyloid tumors. Most importantly, CAEL-101 injection has been shown to specifically bind to the amyloid and not to normal tissue in patients with AL amyloidosis. We hope that this anti-amyloid immunotherapy, in combination with anti-plasma cell chemotherapy, will benefit patients with this fatal disease.”

Dr. Lindsay A. Rosenwald, Fortress Biotech's Chairman, President and Chief Executive Officer, said, "We are thrilled to enter this collaboration with Columbia to advance the development of CAEL-101. The launch of Caelum, Fortress Biotech's eighth subsidiary, underscores our mission of developing a broad pipeline of novel products across areas of unmet need."

CAEL-101 Phase 1a/1b Study Update

Data from an ongoing Phase 1a/1b study ([ClinicalTrials.gov Identifier: NCT02245867](https://clinicaltrials.gov/ct2/show/study/NCT02245867)) have demonstrated that CAEL-101 is well tolerated and safe with no drug-related grade four or five adverse events or dose-limiting toxicity up to 500mg/m². A single infusion of CAEL-101 or one weekly infusion for four weeks have demonstrated early and sustained organ response in cardiac, renal, gastrointestinal, skin and soft tissue. Interim clinical efficacy data show CAEL-101 promotes amyloid resolution in 67 percent of patients (63 percent in Phase 1a; 70 percent in Phase 1b). These data [were presented](#) by Columbia University on December 5, 2016 at the American Society of Hematology's (ASH) 58th Annual Meeting.

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 the principle investigator on the Phase 1a/1b study, said, "These interim results demonstrate strong biomarker activity that may speak to CAEL-101's ability to safely promote amyloid elimination and the subsequent improvement of organ function. We look forward to working with Caelum on this promising program and expect to report full Phase 1a/1b data in the first half of 2017 and initiate a Phase 2 study in 2018."

Michael Spector Named Chief Executive Officer

Michael Spector joins Caelum from Fortress, Caelum's parent company. At Fortress, Michael has leveraged his more than 25 years of experience in biotechnology to identify emerging and innovative technologies to launch as new biotech and specialty pharmaceutical companies. Before joining Fortress, Mr. Spector served as Senior Vice President, Global Commercial Operations at Iroko Pharmaceuticals. Earlier in his career, he spent 15 years at GlaxoSmithKline in multiple senior management positions, including Vice President and General Manager of GlaxoSmithKline South Africa, where he led the overall business strategy and was elected to run the South African Pharmaceutical Manufacturers Association. Mr. Spector is also a founding member of Windhoek Healthcare, where he launched two specialty pharmaceutical companies: Laurel Pharmaceuticals and North Creek Pharmaceuticals.

Mr. Spector holds an M.B.A. from Rider University in Lawrenceville, N.J., where he serves on the school's Business and Scientific Advisory Boards, and a B.S. in biology from the University of Pittsburgh. He also serves on the board of Jacaranda Health, a nonprofit organization that seeks to transform maternal and neonatal healthcare in East Africa.

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 of its subsidiary companies, also known as Fortress Companies. Additionally, Fortress recently acquired a controlling interest in National Holdings Corporation (NASDAQ: NHLD), a diversified independent brokerage company (together with its subsidiaries, "NHLD"). 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. 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 related to our growth strategy; risks relating to the results of research and development activities; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; 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 may be required by law.

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