Fortress Biotech Announces Orphan Drug Designations for CAEL-101 in Amyloidosis

FDA acknowledges transfer to Caelum Biosciences, a Fortress Biotech Company

New York, NY – April 5, 2017 – Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced that the U.S. Department of Health & Human Services has confirmed the transfer of two U.S. Food and Drug Administration (FDA) Orphan Drug Designations for CAEL-101 (also known as 11-1F4) from Columbia University ("Columbia") to Fortress' subsidiary, Caelum Biosciences, Inc. ("Caelum"). The two Orphan Drug Designations include the use of CAEL-101 as a therapeutic agent for patients with AL amyloidosis, and the use of CAEL-101 as a radio-imaging agent in amyloidosis. Caelum in-licensed CAEL-101 from Columbia in January 2017.

CAEL-101 is a fibril-reactive monoclonal antibody (mAb) currently being evaluated in a Phase 1b study for the treatment of AL amyloidosis, 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.

Dr. Lindsay A. Rosenwald, Fortress Biotech's Chairman, President and Chief Executive Officer, said, "The transfer of these two Orphan Drug Designations is significant for Caelum, as they will provide additional market exclusivity and financial benefits that will enable Caelum to advance CAEL-101 as a potential improved treatment option to AL amyloidosis patients in need. Preliminary data for CAEL-101 has demonstrated biomarker activity in a Phase 1a/1b study that may indicate the therapy's ability to safely promote amyloid elimination and the subsequent improvement of organ function. We look forward to reporting full data from the Phase 1a/1b study later this year, and plan to initiate a Phase 2 study in 2018."

FDA Orphan Drug Designation is granted to investigational therapies that address rare medical diseases or conditions that affect fewer than 200,000 people in the U.S. Orphan Drug status provides benefits to drug developers including assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees and seven years of marketing exclusivity.

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, a rare systemic disorder that results in the buildup of misfolded amyloid proteins in and around tissues, nerves and organs, gradually affecting their function. Interim Phase 1a/1b data presented at the American Society of Hematology's (ASH) 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 (FDA) 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 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, 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; 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; 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.

Contacts:

Lucy Lu, M.D., Executive Vice President & Chief Financial Officer
Fortress Biotech, Inc.
781-652-4500; ir@fortressbiotech.com

Fortress Biotech Media Relations
Laura Bagby
6 Degrees
(312) 448-8098; lbagby@6degreespr.com