Fortress Biotech Announces Oral and Poster Data Presentations at the 62nd American Society of Hematology (ASH) Annual Meeting

Clinical data on CAEL-101 for AL amyloidosis and MB-106 CD20-targeted CAR T cell therapy to be presented

NEW YORK, Nov. 04, 2020 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), an innovative revenue-generating company focused on acquiring, developing and commercializing or monetizing promising biopharmaceutical products and product candidates cost-effectively, today announced that data from two of its clinical programs have been accepted for presentation at the 62nd American Society of Hematology (ASH) Annual Meeting, which is being held virtually from December 5 – 8, 2020.

Phase 2 data on Caelum Biosciences’ (“Caelum”) CAEL-101 for the treatment of relapsed or refractory amyloid light chain “AL” amyloidosis will be presented by the Cleveland Clinic during oral and poster sessions. CAEL-101, which is being developed in a collaboration between Caelum, a company founded by Fortress, and Alexion Pharmaceuticals, Inc., recently progressed into Phase 3 development. In addition, interim Phase 1/2 data on Mustang Bio’s (“Mustang”) MB-106, a CD20-targeted, autologous chimeric antigen receptor (CAR) T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas, will be presented by Mustang’s research partner Fred Hutchinson Cancer Research Center (“Fred Hutch”) during a poster session.

Lindsay A. Rosenwald, M.D., Fortress’ Chairman, President and Chief Executive Officer, said, “We are looking forward to data from two of our clinical programs being presented in oral and poster sessions at the ASH Annual Meeting. CAEL-101 and MB-106 are important product candidates that are poised to fill the urgent need for new treatment options and make a meaningful difference for patients.”

Details of the presentations are as follows:

**CAEL-101 Oral Presentation:**

**Title:** Safety, Tolerability and Efficacy of CAEL-101 in AL Amyloidosis Patients Treated on a Phase 2, Open-Label, Dose Selection Study to Evaluate the Safety and Tolerability
CAEL-101 Poster Presentation:

Title: **CAEL-101 Is Well-Tolerated in AL Amyloidosis Patients Receiving Concomitant Cyclophosphamide-Bortezomib-Dexamethasone (CyborD): A Phase 2 Dose-Finding Study (NCT04304144)**

Abstract: 729

Date and Time: Monday, December 7, 2020, 5:45 p.m. ET

Presenter: Jason Valent, M.D., Clinical Assistant Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University; Staff Department of Hematology and Oncology, Director Multiple Myeloma Program, Taussig Cancer Institute, Co-Director Amyloidosis Center, Cleveland Clinic

MB-106 Poster Presentation:

Title: **Third Generation CD20 Targeted CAR T-Cell Therapy (MB-106) for Treatment of Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma**

Abstract: 2277

Date and Time: Sunday, December 6, 2020, 10:00 a.m. - 6:30 p.m. ET

Presenter: Jason Valent, M.D., Clinical Assistant Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University; Staff Department of Hematology and Oncology, Director Multiple Myeloma Program, Taussig Cancer Institute, Co-Director Amyloidosis Center, Cleveland Clinic

For more information, please visit the 62nd ASH Annual Meeting and Exposition website at [https://www.hematology.org/meetings/annual-meeting/abstracts](https://www.hematology.org/meetings/annual-meeting/abstracts).

About CAEL-101 (Light Chain Fibril-reactive Monoclonal Antibody for AL Amyloidosis)

CAEL-101 is a first-in-class monoclonal antibody (mAb) designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis. The antibody is designed to bind to misfolded light chain protein and amyloid and shows binding to both kappa and lambda subtypes. In a Phase 1a/1b study, CAEL-101 demonstrated improved organ function, including cardiac and renal function, in 27 patients with relapsed and refractory AL amyloidosis who had previously not had an organ response to standard of care therapy. CAEL-101 has received Orphan Drug Designation from both the U.S. Food and Drug Administration and European Medicine Agency as a therapy for patients with AL amyloidosis.

About Caelum Biosciences
Caelum Biosciences, Inc. ("Caelum") is a clinical-stage biotechnology company developing treatments for rare and life-threatening diseases. Caelum’s lead asset, CAEL-101, is a novel antibody for the treatment of patients with amyloid light chain ("AL") amyloidosis. In 2019, Caelum entered a collaboration agreement with Alexion under which Alexion acquired a minority equity interest in Caelum and an exclusive option to acquire the remaining equity in the company based on Phase 3 CAEL-101 data. Caelum was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.caelumbio.com.

About MB-106 (CD20-targeted CAR T Cell Therapy)
CD20 is a membrane-embedded surface molecule which plays a role in the differentiation of B-cells into plasma cells. The CAR T was developed by Mustang’s research partner, Fred Hutchinson Cancer Research Center ("Fred Hutch"), in the laboratory of Oliver Press, M.D., Ph.D., and Brian Till, M.D., in the Clinical Research Division and exclusively licensed to Mustang Bio in 2017. MB-106 has been optimized as a third-generation CAR derived from a fully human antibody and is currently in a Phase 1/2 open-label, dose-escalation trial at Fred Hutch in B-cell non-Hodgkin lymphoma patients. Additional information on the trial can be found at http://www.clinicaltrials.gov using the identifier NCT03277729.

About Mustang Bio
Mustang Bio, Inc. is a clinical-stage biopharmaceutical company focused on translating today’s medical breakthroughs in cell and gene therapies into potential cures for hematologic cancers, solid tumors and rare genetic diseases. Mustang aims to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, to fund research and development, and to outlicense or bring the technologies to market. Mustang has partnered with top medical institutions to advance the development of CAR T therapies across multiple cancers, as well as a lentiviral gene therapy for X-linked severe combined immunodeficiency (XSCID), also known as bubble boy disease. Mustang is registered under the Securities Exchange Act of 1934, as amended, and files periodic reports with the U.S. Securities and Exchange Commission ("SEC"). Mustang was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.mustangbio.com.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress") is an innovative biopharmaceutical company that was ranked number 10 in Deloitte’s 2019 Technology Fast 500™, an annual ranking of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentage of fiscal year revenue growth over a three-year period. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage drugs and drug candidates. The company has five marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company’s portfolio of product opportunities. Fortress has established partnerships with some of the world’s leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion.
Pharmaceuticals, Inc., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, InvaGen Pharmaceuticals Inc. (a subsidiary of Cipla Limited), St. Jude Children’s Research Hospital and Nationwide Children’s Hospital. 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. As used below and throughout this press release, the words “we”, “us” and “our” may refer to Fortress individually or together with one or more partner companies, as dictated by context. 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; risks relating to the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; 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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying mutatis mutandis to every other instance of such information appearing herein.

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