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# Mustang Bio Completes Pre-IND Meeting with FDA for MB-102 (CD123 CAR T)

## IND filing for MB-102 in BPDCN, AML and high-risk myelodysplastic syndrome on track for Q4 2018

NEW YORK, July 19, 2018 (GLOBE NEWSWIRE) -- Mustang Bio, Inc. ("Mustang") (NASDAQ:MBIO), a Fortress Biotech (NASDAQ:FBIO) Company focused on the development of novel immunotherapies based on proprietary chimeric antigen receptor engineered T cell (CAR T) technology, announced today that it has completed a pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) for MB-102 (CD123 CAR T). MB-102 is a CAR T therapy in development for the treatment of acute myeloid leukemia (AML), blastic plasmacytoid dendritic cell neoplasm (BPDCN) and high-risk myelodysplastic syndrome (MDS). Mustang will continue its efforts on its IND filing to the FDA for MB-102.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We are pleased with the FDA's feedback on our development plan and expect to submit an IND filing for MB-102 in the fourth quarter as planned. We anticipate that our manufacturing facility will be ready to process patient cells in the next few months, which will help enable initiation of our Phase 1/2 clinical trial of MB-102 in AML, BPDCN and MDS to begin in 2019, after approval of Mustang's first IND."

#### About MB-102 (CD123 CAR T)

MB-102 (CD123 CAR T) is a CAR T cell therapy that is produced by engineering patient T cells to recognize and eliminate CD123-expressing tumors. CD123 is widely expressed on bone marrow cells of patients with MDS, as well as in hematologic malignancies including AML, B cell acute lymphoblastic leukemia, hairy cell leukemia, BPDCN, chronic myeloid leukemia and Hodgkin's lymphoma.

In the first-in-human clinical trial at City of Hope <u>NCT02159495</u>), MB-102 has demonstrated complete responses at low doses in AML and BPDCN without dose-limiting toxicities, as reported at the American Society of Hematology annual meeting in December 2017. Dose escalation continues at City of Hope in both indications.

#### **About Mustang Bio**

Mustang Bio, Inc. ("Mustang"), a Fortress Biotech Company, is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel cancer immunotherapy products designed to leverage the patient's own immune system to eliminate cancer cells. 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 the City of Hope National Medical Center and the Fred Hutchinson Cancer Research Center to develop proprietary chimeric antigen receptor ("CAR") engineered T cell ("CAR T") therapies across many cancers, and with Harvard Medical School's Beth Israel Deaconess Medical Center and the Harvard Stem Cell Institute for the development of CRISPR/Cas9-enhanced CAR T therapies in hematologic malignancies and solid tumors. Mustang is registered under the Securities Exchange Act of 1934, as amended, and files periodic reports with the U.S. Securities and Exchange Commission. For more information, visit <u>www.mustangbio.com</u>.

#### 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. 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 licensing arrangements, 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, each 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 value. 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; risks relating to the timing of starting and completing clinical trials; 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.

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