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Mustang Bio Announces First Patient Dosed in Multicenter Phase 1/2 Clinical Trial of MB-102 (CD123-targeted CAR T Cell Therapy)

Safety and efficacy to be evaluated in patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm, acute myeloid leukemia and high-risk myelodysplastic syndrome

WORCESTER, Mass., Oct. 01, 2020 (GLOBE NEWSWIRE) -- Mustang Bio, Inc. (“Mustang”) (NASDAQ: MBIO), 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, today announced that the first patient has been dosed in a Mustang-sponsored, open label, multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-102 (CD123-targeted CAR T cell therapy) in patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm (BPDCN), acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (hrMDS). Study sites include City of Hope, where the CAR T cell therapy was initially developed and where the clinical data were generated to support Mustang’s current multicenter trial, Dana-Farber Cancer Institute, Duke University and MD Anderson Cancer Center.

The Phase 1 portion of the trial will determine the maximum tolerated dose of MB-102 for the Phase 2 portion of the trial. Safety will be assessed at each dose level before proceeding to the next. The Phase 2 portion of the trial may be divided into as many as three arms to evaluate the efficacy of MB-102 in relapsed or refractory BPDCN (Arm 1), relapsed or refractory AML (Arm 2) and demethylation resistant hrMDS (Arm 3). The primary outcome that will be studied is the response rate at day 28 post infusion in all arms. Secondary outcome measures include duration of response, progression-free survival, overall survival and incidence of treatment-emergent adverse events, which will be followed for up to three years.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “This is a momentous occasion for Mustang, as it is the first clinical trial under Mustang’s investigational new drug application (IND) in which a patient was dosed with cells processed in our own manufacturing facility. We look forward to advancing the development of MB-102 and providing updates on the trial as we seek to help address the needs of patients suffering

from the devastating diseases of BPDCN, AML and hrMDS."

Additional information about the trial can be found onwww.clinicaltrials.gov using the identifier NCT04109482.

About MB-102 (CD123-targeted CAR T Cell Therapy)
MB-102 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 myelodysplastic syndromes, as well as in hematologic malignancies, including AML, and BPDCN.

In the first-in-human clinical trial at City of Hope (NCT02159495), 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 (ASH) Annual Meeting in December 2017 and the American Association for Cancer Research (AACR) Special Conference on Tumor Immunology and Immunotherapy in November 2018. Dose escalation continues at City of Hope in both indications. MB-102 has received Orphan Drug Designations from the U.S. Food and Drug Administration for AML and BPDCN.

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 XSCID. 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.

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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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