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Mustang Bio Provides CAR T Cell Therapy Portfolio Updates and 2023 Anticipated Milestones

MB-106 clinical trial under Mustang's IND continues to enroll patients

Additional IND filing and published research expected in 2023 across portfolio

WORCESTER, Mass., Dec. 19, 2022 (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 recent CAR T cell therapy portfolio updates and provided anticipated milestones for 2023.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "In 2022, Mustang successfully advanced our CAR T cell therapy portfolio which has laid the foundation for us to achieve multiple milestones in the coming year. Our lead clinical candidate, MB-106, a first-in-class CD20-targeted, autologous CAR T cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHL") and chronic lymphocytic leukemia ("CLL"), continues to progress in our multicenter Phase 1/2 clinical trial. We're pleased to report that Mustang has met its accrual target for the year for that trial and has manufactured product for all enrolled patients. We look forward to providing first safety and efficacy data in 2023. Additionally, data from the initial ongoing Phase 1/2 clinical trial taking place at Fred Hutchinson Cancer Center ("Fred Hutch") continue to exhibit high efficacy and a favorable safety profile compared to currently approved autologous CAR Ts. In particular, while other cell therapies in development have struggled to show durability of response, we reported in October that twelve of 28 patients enrolled had experienced complete remission (CR) for more than 12 months (10 ongoing), four patients had experienced CR for more than 2 years (all ongoing), and the first patient enrolled was in sustained CR at 33 months."

"In 2023, we anticipate filing an Investigational New Drug application ("IND") for our combination therapy MB-109 to treat glioblastoma ("GBM"). Additionally, we continue to collaborate with the Mayo Clinic to progress our exclusively licensed novel *in vivo* CAR T technology platform and anticipate the publication of proof-of-concept research in a murine tumor model. We're looking forward to another productive year across our CAR T therapy programs, as we continue working with our world-class partners to advance therapies for difficult-to-treat cancers and rare diseases," said Dr. Litchman.

CAR T Candidate Portfolio Highlights:

MB-106 (first-in-class CD20-targeted, autologous CAR T cell therapy)
To date, six patients have been enrolled in Mustang's multicenter Phase 1/2 clinical trial and five patients have been infused at the starting dose levels of their respective protocol arms. Mustang has successfully manufactured product for all enrolled patients at its facility in Worcester, MA. In 2023, the Company anticipates dose escalation and reporting response data at a major medical meeting.

As previously reported, MB-106 continues to demonstrate high efficacy and a favorable safety profile across patients with a wide range of hematologic malignancies in a Phase 1 investigator-sponsored trial at Fred Hutch, including a 100% overall response rate in patients with Waldenstrom macroglobulinemia ("WM"), a rare form of blood cancer. Given this, Mustang plans to treat patients with WM in the Phase 1 portion of its multicenter clinical trial to support a fast-to-market Phase 2 strategy for this indication. Data from the Fred Hutch clinical trial also support the potential of MB-106 to be administered as outpatient therapy and provide a best-in-class immunotherapy option for patients treated previously with CD19-directed CAR T cell therapy. In 2023, Mustang anticipates the U.S. Food and Drug Administration granting Orphan Drug Designation in at least one additional CD20 positive malignancy.

MB-109 (MB-101 (IL-13Rα2 targeted CAR T cell therapy) + MB-108 oncolytic virus)
Preclinical data presented at American Association for Cancer Research Annual Meeting 2022 ("AACR") supported this combination therapy to optimize results to treat recurrent GBM. The combination leverages MB-108 to make cold tumors "hot," thereby improving the efficacy of MB-101 CAR T cell therapy. Data presented separately on MB-101 and MB-108 showed infusions were well tolerated in highly refractory GBM patients. Two patients treated solely with MB-101 who had high levels of intratumoral CD3+ T cells pre-therapy (i.e., "hot" tumors) achieved complete responses lasting 7.5 and 31+ months, respectively. Phase 1 clinical trials of MB-101 at City of Hope and of MB-108 at the University of Alabama at Birmingham continue to enroll patients. Additionally, Mustang will advance the preclinical investigation of MB-109 and plans to file an IND for this treatment in 2023.

MB-102 (CD123-targeted CAR T cell therapy)
The Safety Review Team ("SRT") composed of Investigators and Mustang representatives recently met to assess the progress and safety data from the ongoing Mustang-sponsored, open label, multicenter Phase 1/2 clinical trial to evaluate the safety and efficacy of MB-102 in patients with relapsed or refractory blastic plasmacytoid dendritic cell neoplasm ("BPDCN"), a rare form of leukemia. After thoroughly reviewing the safety data from Dose Level 1 (100×10^6 CAR T cells), the SRT unanimously recommended dose escalation to Dose Level 2 (300×10^6 CAR T cells). There are currently no curative treatments for BPDCN. The trial continues to enroll and study sites include City of Hope, where the CAR T cell therapy was initially developed, Dana-Farber Cancer Institute, Duke University and The University of Texas MD Anderson Cancer Center. The MB-102 clinical trial is the first under Mustang's IND in which a patient was dosed with cells processed in its own manufacturing facility. In 2023, Mustang expects to provide information about Dose Level 2 after that level is fully enrolled and the SRT has reviewed the data.

In vivo CAR-T platform technology

Mustang executed an exclusive license agreement with Mayo Clinic for this novel technology that may transform the administration of CAR T therapies. The Mayo approach involves activating immune cells *in vivo* using natural methods employed by the body to deal with infection, thus having the potential to reduce toxicities associated with traditional CAR T therapy. Successful implementation of this technology could lead to an off-the-shelf product with no need to isolate and expand patient T cells *ex vivo* in a manufacturing facility. Published proof-of-concept data from murine tumor model studies are anticipated in 2023. Additionally, Mustang plans to file an IND application for a multicenter Phase 1 clinical trial once a lead CAR construct has been identified.

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 lentiviral gene therapies for severe combined immunodeficiency. Mustang's common stock is registered under the Securities Exchange Act of 1934, as amended, and Mustang 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 contains "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, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions, include, but are not limited to, any statements relating to our growth strategy and product development programs, including the timing of and our ability to make regulatory filings such as INDs and other applications and to obtain regulatory approvals for our product candidates, statements concerning the potential of therapies and product candidates, 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 Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K filed on March 23, 2022, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. 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.

Company Contact:
Jaclyn Jaffe
Mustang Bio, Inc.
(781) 652-4500
ir@mustangbio.com

Investor Relations Contact:
Daniel Ferry
LifeSci Advisors, LLC
(617) 430-7576
daniel@lifesciadvisors.com

Media Relations Contact:
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

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