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Mustang Bio Announces First Data from Ongoing Multicenter Phase 1/2 Clinical Trial Evaluating MB-106 CAR-T Cell Therapy

Initial data show clinical responses from four of four indolent lymphoma patients, including complete response in follicular lymphoma patient previously treated with CD19 CAR-T cell therapy

Aligns with ongoing results from investigator-sponsored trial at Fred Hutchthat show ongoing complete remission for more than three years

Update on data presented at 5th iwCAR-T, Scottsdale, AZ

Safety Review Committee unanimously approved dose escalation of the indolent lymphoma arm

WORCESTER, Mass., Aug. 16, 2023 (GLOBE NEWSWIRE) -- Mustang Bio, Inc. (“Mustang” or the “Company”) (Nasdaq: MBIO), a clinical-stage biopharmaceutical company focused on translating today’s medical breakthroughs in cell and gene therapies into potential cures for difficult-to-treat cancers and rare genetic diseases, today announced the first data from the indolent lymphoma cohort of the Company’s ongoing multicenter Phase 1/2 clinical trial evaluating 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”), demonstrating clinical responses as well as safety and efficacy consistent with the ongoing Phase 1/2 clinical trial taking place at Fred Hutchinson Cancer Center (“Fred Hutch”).

Initial data were presented by Mazyar Shadman, M.D., M.P.H., Study Chair, Associate Professor and physician at Fred Hutch and University of Washington, at the 5th International Workshop on CAR-T and Immunotherapies (“*iw*CAR-T”).

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “We are encouraged that the first data from the multicenter trial of our lead candidate, MB-106, show clinical responses and that the trial is on track to achieve results consistent with those from the ongoing trial taking place at Fred Hutch. Overall, MB-106 continues to exhibit high efficacy and a favorable safety profile compared to currently approved autologous CAR-Ts.

We expect to provide an additional update on dose escalation and report response data at a major medical meeting later this year."

The multicenter study data show clinical responses in four of four patients with relapsed or refractory indolent NHL at the starting dose of 3.3 x 10^6 CAR-T cells/kg, a dose comparable to that employed for the majority of the indolent lymphoma patients in the Fred Hutch trial. The multicenter data also show persistence of CAR-T cells at 6+ months and favorable safety data with only Grade 1 cytokine release syndrome ("CRS") reported to date. Two patients with follicular lymphoma had complete response ("CR") by both PET-CT and bone marrow, one of whom had been previously treated with a CD19-directed CAR-T. A third patient, with a diagnosis of Waldenstrom macroglobulinemia ("WM"), who had nine prior treatments and high disease burden, achieved complete metabolic response by PET-CT, morphologic clearance of lymphoma in bone marrow, and resolution of the IgM monoclonal protein. The fourth patient, with a diagnosis of hairy cell leukemia variant, who had been heavily transfusion dependent, continues to have stable disease with decreased disease in his bone marrow and achieved complete transfusion independence, which is ongoing at 6+ months.

Following treatment of the four indolent NHL patients, the Safety Review Committee unanimously approved dose escalation to 1.0 x 10^7 CAR-T cells/kg.

"MB-106 continues to show potential as an immunotherapy option for patients with a wide range of hematologic malignancies, including patients previously treated with CD19-directed CAR-T cell therapy," said Mazyar Shadman, M.D., M.P.H., who holds the Innovators Network Endowed Chair at Fred Hutch and is the Study Chair, as well as Associate Professor and physician at Fred Hutch and University of Washington. "We are excited that the first data from the expanded evaluation of MB-106 are similar in safety as what we've seen to date in the ongoing Phase 1/2 clinical trial at Fred Hutch. Additionally, the data from the ongoing clinical trial at Fred Hutch continue to demonstrate a high rate of complete and durable responses."

Dr. Shadman also presented data from the ongoing Fred Hutch Phase 1/2 clinical trial, specific to two B-NHL cohorts, follicular lymphoma ("FL") and WM. In the FL data cohort (n=20), an overall response rate ("ORR") of 95% was seen, of which 80% of patients experienced a CR, and 15% had a partial response. The CR patients include a patient who was previously treated with a CD19-directed CAR-T cell therapy. Of the six patients who experienced CRS, only one had Grade 2. Ten patients continue to experience CR for more than 10 months, four patients have experienced CR for more than two years (all ongoing), and the first patient enrolled has sustained CR for more than 3 years. In the WM cohort (n=6), all of whom had received prior Bruton tyrosine kinase inhibitor, two patients experienced CR, one of whom continues to be in CR at more than 22 months. No patients experienced CRS or immune effector cell-associated neurotoxicity syndrome over Grade 2. None of the six WM patients have needed to start new therapy for their disease.

As previously reported, 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 and received Orphan Drug Designation from the U.S. Food and Drug Administration ("FDA"). There is currently no FDA-approved CAR-T cell therapy for WM, and the first patient in the pivotal Phase 2 WM trial is expected to be treated in mid-2024, which could enable top-line

data as early as mid-2026. By the end of 2023, we anticipate confirming this strategy at an end-of-Phase 1 meeting with the US Food and Drug Administration (FDA). Furthermore, Mustang anticipates requesting regenerative medicine advanced therapy (RMAT) designation for WM from the FDA in 2024. Finally, 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.

About Mustang's Multicenter MB-106 Phase 1/2 Clinical Trial

The five-center Phase 1/2 clinical trial is a three-arm study targeting CLL and B-NHL, including FL, diffuse large B-cell lymphoma and mantle cell lymphoma. We anticipate adding a sixth center by the end of 2023. The Mustang-sponsored multicenter clinical trial is using the same lentiviral vector as the Fred Hutch-sponsored single-center trial. Included in the eligibility criteria are patients who have relapsed after treatment with CD19 CAR-T cell therapy. Additionally, the FL arm will evaluate other indolent histologies including Waldenstrom macroglobulinemia, a rare type of B-NHL for which the U.S. Food and Drug Administration granted MB-106 Orphan Drug Designation. Patients will be enrolled in one of three arms, based on their primary diagnosis; escalating MB-106 dose levels will be tested independently in each arm using a 3+3 design.

A total of up to 18 patients are anticipated to be treated in each Phase 1 arm, including six patients at the maximum tolerated dose in each independent arm. Safety of each dose level will be reviewed for each arm until the maximum tolerated dose has been reached and the recommended Phase 2 dose ("RP2D") has been established for each arm. An assessment of the safety and tolerability of the dose will be made by the Safety Review Committee based on the data from the 28-day dose-limiting toxicity observation period.

In Phase 2, specific arms of relapsed or refractory CD20-positive B-cell hematologic malignancies will be treated with MB-106 at the respective RP2D for each arm. The two top priorities are WM and diffuse large B-cell lymphoma (DLBCL) relapsed from prior CD19 CAR-T therapy. Each arm will initially include up to 20 patients. Based on the results of the interim analysis, up to an additional 51 patients may be added to each of the arms.

Additional information about the trial can be found on clinicaltrials.gov using the identifier NCT05360238.

About MB-106 (CD20-targeted autologous 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 collaborator, Fred Hutch, in the laboratories of the late Oliver Press, M.D., Ph.D., and Brian Till, M.D., Associate Professor in the Clinical Research Division at Fred Hutch, and was exclusively licensed to Mustang in 2017. The lentiviral vector drug substance used to transduce patients' cells to create the MB-106 drug product produced at Fred Hutch has been optimized as a third-generation CAR derived from a fully human antibody. MB-106 is currently in a Phase 1/2 open-label, dose-escalation trial at Fred Hutch in patients with B-NHLs and CLL. The same lentiviral vector drug substance produced at Fred Hutch is used to transduce patients' cells to create the MB-106 drug product produced at Mustang Bio's Worcester, MA, cell processing facility for administration in the multicenter Phase 1/2 clinical trial under Mustang

Bio's IND. It should be noted that Mustang Bio has introduced minor improvements to its cell processing to facilitate eventual commercial launch of the product. In addition, prior to commercial launch, Mustang Bio will replace the Fred Hutch lentiviral vector drug substance with vector produced at a commercial manufacturer. Additional information on the trials can be found at http://www.clinicaltrials.gov using the identifier NCT05360238 for the multicenter trial and NCT03277729 for the ongoing trial at Fred Hutch. On May 18, 2023 Mustang Bio entered into an Asset Purchase Agreement, as amended by the First Amendment, dated as of June 29, 2023 and a Second Amendment, dated as of July 28, 2023 pursuant to which it agreed to sell its assets primarily pertaining to the manufacturing and production of cell and gene therapies located at its cell processing facility in Worcester, MA; and, subject to the satisfaction of certain conditions, its leasehold interest in that facility. Concurrent with the Second Amendment, Mustang closed the transaction under the terms of the amended asset purchase agreement and entered into manufacturing services agreements with the purchaser to provide for the continued production of the MB-106 drug product. For additional information, please refer to the Form 8-Ks filed by Mustang Bio with the U.S. Securities and Exchange Commission ("SEC") on May 22, 2023, June 30, 2023 and July 31, 2023.

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 difficult-to-treat cancers 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. The Company's forward-looking statements, 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. Actual events or results may differ materially from those described in this press release due to a number of risks and uncertainties. Risks and uncertainties include, among other things, risks related to whether the Company's third-party manufacturer is able to successfully perform its obligation to produce the Company's products under the manufacturing services agreement on a timely basis and to acceptable standards; disruption from the sale of the Company's manufacturing facility making it more difficult to maintain business and

operational relationships; negative effects of the announcement of the consummation of the sale of the Company's manufacturing facility on the market price of the Company's common stock; significant transaction costs; the development stage of the Company's primary product candidates, 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 30, 2023, 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.

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