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Mustang Bio Announces Updated Results from Waldenstrom Macroglobulinemia Cohort of Ongoing Phase 1/2 Clinical Trial of MB-106, CD20-Targeted Autologous CAR T Therapy

MB-106 continues to demonstrate favorable safety and efficacy profile

Overall response rate of 83% in cohort with durable responses observed; one patient remains in complete remission at 22 months

All patients were refractory to BTK inhibitors, and no patients have started new anti-WM treatment after MB-106

Currently no FDA-approved CAR T treatments for WM

WORCESTER, Mass., June 12, 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 that updated data from the ongoing Phase 1/2 clinical trial of MB-106, a CD20-targeted, autologous CAR T cell therapy, show a favorable safety and efficacy profile in patients with Waldenstrom macroglobulinemia ("WM"), a rare form of blood cancer. MB-106 is being developed in a collaboration between Mustang and Fred Hutchinson Cancer Center ("Fred Hutch") to treat patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHLs") and chronic lymphocytic leukemia ("CLL").

The updated results from the single-institution Phase 1/2 clinical trial were presented during a poster session at the European Hematology Association 2023 Hybrid Congress ("EHA2023") by Mazyar Shadman, M.D., M.P.H., Associate Professor and physician at Fred Hutch and University of Washington.

"As we continue to evaluate MB-106 in this single-institution study, we're encouraged by its potential to become an outpatient treatment option for WM and other B-cell malignancies, including indolent and aggressive non-Hodgkin lymphomas," said Dr. Shadman. "We have observed ongoing responses to MB-106 with improvements in the quality of response over

time, along with a favorable safety profile.”

All six patients in the study were previously treated with Bruton's tyrosine kinase inhibitors (“BTKi”), and their disease continued to progress while on BTKi's. Overall, 83% (5/6) of the patients treated with MB-106 responded to treatment, including 2 complete responses, 1 very good partial response, 1 partial response, and 1 minor response. In addition, 1 patient experienced stable disease. One of the patients who achieved a complete response has remained in remission for 22 months, with an immunoglobulin M (IgM) level that decreased rapidly to the normal range after treatment with MB-106 and has remained normal since. No patient has started additional anti-WM treatment after being treated with MB-106. From a safety perspective, cytokine release syndrome (CRS) occurred in five patients: two patients with grade 1 and three patients with grade 2. One patient experienced grade 1 immune effector cell-associated neurotoxicity syndrome (ICANS). No grade 3 or 4 CRS or grade 2, 3 or 4 ICANS has been observed.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, commented, “MB-106 has the potential to fill a significant unmet need, as there are currently no CAR T treatments for WM approved by the U.S. Food and Drug Administration (“FDA”). The MB-106 data from the Phase 1/2 clinical trial taking place at Fred Hutch continue to be encouraging for WM and other B-NHLs. The positive data from this study and the FDA Orphan Drug Designation MB-106 received for WM support the treatment of patients with WM in the Phase 1 portion of our multicenter Phase 1/2 clinical trial which is underway and also support a fast-to-market Phase 2 strategy for this indication. We plan to report initial clinical data from the multicenter program shortly.”

For more information on the clinical trials, please visit www.clinicaltrials.gov using the identifier [NCT05360238](https://clinicaltrials.gov/ct2/show/study/NCT05360238) for the multicenter trial and [NCT03277729](https://clinicaltrials.gov/ct2/show/study/NCT03277729) for the ongoing trial at Fred Hutch.

Scientists at Fred Hutch played a role in developing these discoveries, and Fred Hutch and certain of its scientists may benefit financially from this work in the future.

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, and 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 being 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 that is now open to enrollment 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](https://clinicaltrials.gov/ct2/show/study/NCT05360238) for the multicenter trial

and [NCT03277729](#) for the ongoing trial at Fred Hutch. Mustang Bio has entered into an Asset Purchase Agreement pursuant to which it has agreed to sell, subject to the satisfaction of certain conditions, its leasehold interest in its cell processing facility and expects to enter into a manufacturing services agreement with the prospective purchaser to provide for the continued production of the MB-106 drug product. For additional information, please refer to the Current Report on Form 8-K filed by Mustang Bio with the U.S. Securities and Exchange Commission (“SEC”) on May 22, 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 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, statements about the Company’s expectations with respect to the consummation of the sale of its manufacturing facility, its entry into a manufacturing services agreement with the prospective purchaser of the facility and its ability to obtain its MB-106 drug product pursuant to such manufacturing services agreement 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 the satisfaction of the conditions to closing the sale of the Company’s manufacturing facility in the anticipated timeframe or at all; whether the prospective purchaser of the Company’s manufacturing facility 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 or the consummation of the transaction 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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