

June 13, 2022



## **Mustang Bio Announces Updated Interim Results from Follicular Lymphoma Cohort of Ongoing Phase 1/2 Clinical Trial of MB-106, CD20-Targeted CAR T Therapy**

*94% overall response rate and 78% complete response rate in patients with FL, including complete response in a patient previously treated with CD19-targeted CAR T therapy*

*100% overall response rate in other B-cell non-Hodgkin lymphomas including Waldenstrom macroglobulinemia and diffuse large B-cell lymphoma*

*Multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL under Mustang's IND open to enrollment*

WORCESTER, Mass., June 13, 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 that updated interim data from the ongoing Phase 1/2 clinical trial of MB-106, a CD20-targeted, autologous CAR T cell therapy, show a favorable safety profile, high overall response ("ORR") and complete response ("CR") rates, and CAR T persistence in patients with follicular lymphoma ("FL"). 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 presented during an on-site oral presentation at the European Hematology Association 2022 Hybrid Congress ("EHA2022") by Mazyar Shadman, M.D., M.P.H., Associate Professor and physician at Fred Hutch and University of Washington, included interim safety and efficacy data from the cell manufacturing process that was modified to combine the culture of CD4+ and CD8+ cells. CAR-T cells were administered at one of 5 dose levels:  $1 \times 10^5$ ,  $3.3 \times 10^5$ ,  $1 \times 10^6$ ,  $3.3 \times 10^6$  and  $1 \times 10^7$  CAR T cells/kg. Treatment for all patients was infused in the outpatient setting except for the first patient of each dose cohort, each of which was kept for overnight observation.

In the 18 treated patients with FL, ORR and CR were 94% (17/18) and 78% (14/18), respectively. Additionally, 17% experienced a partial response (3/18) and 5% experienced

disease progression (1/18). One patient experienced pseudo-progression followed by a spontaneous CR documented at 207 days and has remained in remission since. Additionally, one patient with prior CD19 CAR-T failure experienced a CR and also remains in remission. From a safety profile perspective, cytokine release syndrome occurred in 5 patients: 4 patients with grade 1 and one patient with grade 2. No patients with FL experienced immune effector cell associated neurotoxicity syndrome of any grade. Although the persistence of CAR T cells was seen at all dose levels and was comparable by day 28, the expansion was faster at the higher dose levels.

“We continue to observe a favorable safety profile and high rate of complete response with MB-106 as exhibited by this follicular lymphoma cohort and within a wide range of other hematologic malignancies including CLL, diffuse large B-cell lymphoma (“DLBCL”) and Waldenstrom macroglobulinemia (“WM”),” said Dr. Shadman. “Based on the ongoing progress, MB-106 may be a suitable outpatient treatment for these patients and another immunotherapy option for patients for whom CD19-directed CAR T cell therapy is not effective. Enrollment in this study remains open to patients with CD20+ B-NHLs and CLL, including patients with prior CAR T treatment.”

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “Given the ongoing positive progress presented by Dr. Shadman, we look forward to evaluating MB-106 to treat relapsed or refractory B-NHL and CLL in the multicenter clinical trial under Mustang’s IND which is now open to enrollment. MB-106 continues to demonstrate its potential as a safe, effective CAR T therapy that can address the unmet needs of a range of patients with relapsed or refractory B-NHLs, including WM and DLBCL, with outpatient administration. It is especially gratifying to see that the DLBCL patient previously reported as a PR has now improved to a CR, which therefore represents a second CR in DLBCL and a second CR in a patient previously treated with CD19-targeted CAR T therapy.”

For more information on the clinical trials, please visit [www.clinicaltrials.gov](http://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 will be 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 planned 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](#) for the multicenter trial and [NCT03277729](#) for the ongoing trial at Fred Hutch.

### **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 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](http://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.

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Source: Mustang Bio, Inc.