

November 4, 2021



## **Mustang Bio Announces MB-106 CD20-Targeted CAR T Data Selected for Presentation at 63rd American Society of Hematology (ASH) Annual Meeting**

**Key opinion leader webinar on Thursday, December 16, 2021, at 2:30 p.m. ET**

WORCESTER, Mass., Nov. 04, 2021 (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 interim Phase 1/2 data on MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL") and chronic lymphocytic leukemia ("CLL"), have been selected for a poster presentation at the 63<sup>rd</sup> American Society of Hematology Annual Meeting ("ASH2021"), which is being held from December 11-14, 2021. MB-106 is being developed in a collaboration between Mustang and Fred Hutchinson Cancer Research Center ("Fred Hutch").

The abstract posted today on the ASH2021 website reported on 16 patients [12 follicular lymphoma ("FL"), 2 mantle cell lymphoma ("MCL"), 1 CLL and 1 diffuse large B-cell lymphoma ("DLBCL")] treated following a major cell manufacturing process modification. CAR T cells are administered at one of 4 dose levels ("DL"): DL1:  $3.3 \times 10^5$ , DL2:  $1 \times 10^6$ , DL3:  $3.3 \times 10^6$ , DL4:  $1 \times 10^7$  CAR T cells/kg. All DLs were reached, with no dose-limiting toxicities observed to date.

The overall response rate ("ORR") was 94% (15/16) with a complete response ("CR") rate of 62% (10/16). In patients with FL (n=12), ORR was 92% (11/12) and CR rate was 75% (9/12). Among patients with FL who received DL 3 or 4, the CR rate was 86%. The patient with CLL had a PET-negative CR and undetectable measurable residual disease in peripheral blood and bone marrow by flow cytometry at a sensitivity of  $10^{-4}$  (uMRD4) on day 28. The patient with DLBCL achieved a partial response ("PR") on day 28, and a repeat PET on day ~90 showed deepening of the PR. Among patients who achieved a CR, only one patient with FL relapsed after 9 months. All other CRs are ongoing (range: 3-18 months). CAR T persistence was lost at day 95 in one patient who had progression and proceeded to other anti-lymphoma treatment; 2 other patients lost CAR T engraftment by day 181 and 201

with B-cell recovery. All other patients continue to have detectable CAR T cells as of last follow-up (maximum of 13 months post-infusion).

Among the 16 total patients reported in the abstract, there were seven occurrences of cytokine release syndrome (4 patients with Grade 1 and 3 patients with Grade 2) and one occurrence of Grade 2 immune effector cell-associated neurotoxicity syndrome. One patient with CLL developed Grade 3 temporary neuropathic pain which, in the absence of other explanation, was attributed to CAR T therapy. No patients had tumor lysis syndrome or Grade 3-4 infections. Thrombocytopenia (Grade 3-4: 19%) and neutropenia (Grade 3-4: 94%) were common, but there were no bleeding complications, and the rate of febrile neutropenia was 19%.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “The encouraging data from the ongoing Phase 1/2 trial of MB-106 at Fred Hutch highlighted in the ASH2021 abstract strengthen the MB-106 safety and efficacy profile previously reported at the European Hematology Association 2021 Congress in June 2021. The additional data from the 16 patients disclosed today further indicate that MB-106 has a favorable safety profile as outpatient therapy, with compelling clinical activity, ongoing durable complete responses, and a high rate of CAR T persistence. We look forward to Fred Hutch’s updated data presentation at ASH2021 and to continuing to progress our MB-106 CD20-targeted CAR T cell therapy program under Mustang’s IND for patients with relapsed or refractory B-cell non-Hodgkin lymphomas and chronic lymphocytic leukemia.”

Details of the presentation are as follows:

**Title:** [Safety and Efficacy of Third Generation CD20 Targeted CAR-T \(MB-106\) for Treatment of Relapsed/Refractory B-NHL and CLL](#)

**Session:** 704. Cellular Immunotherapies: Clinical: Poster III

**Abstract:** 3872

**Date and Time:** Monday, December 13, 2021, 6:00 p.m. - 8:00 p.m. ET

**Presenter:** Mazyar Shadman, M.D., M.P.H., Associate Professor, Clinical Research Division, Fred Hutch, Seattle, WA; Physician at Seattle Cancer Care Alliance; Associate Professor, Division of Medical Oncology, University of Washington School of Medicine

For more information, please visit the 63<sup>rd</sup> ASH Annual Meeting and Exposition website at <https://www.hematology.org/meetings/annual-meeting/abstracts>.

### **Webinar**

On Thursday, December 16, 2021, at 2:30 p.m. ET, Mustang will host a webinar with Dr. Shadman and colleague Brian Till, M.D., both of Fred Hutch, to discuss the updated interim results from the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 CD20-targeted CAR T for B-NHL and CLL. Mustang’s management team will also provide more details on the planned MB-106 Phase 1/2 clinical trial to be conducted under Mustang’s Investigational New Drug (“IND”) application. The U.S. Food and Drug Administration (“FDA”) has accepted Mustang’s IND to initiate a multicenter Phase 1/2 clinical trial investigating the safety, tolerability and efficacy of MB-106 for relapsed or refractory B-NHL and CLL. Following the formal presentations, the Mustang team, along with Drs. Till and Shadman, will be available for questions. To register for the webinar, please [click here](#). An archived replay will be accessible on the Events page of the Investor Relations section of Mustang’s website: [www.mustangbio.com](http://www.mustangbio.com) for approximately 30 days following the

call.

### **About MB-106 (CD20-targeted 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, and exclusively licensed to Mustang in 2017. MB-106 has been optimized as a third-generation CAR derived from a fully human antibody and is currently in a Phase 1/2 open-label, dose-escalation trial at Fred Hutch in patients with B-NHL and CLL. Additional information on the trial can be found at <http://www.clinicaltrials.gov> using the identifier [NCT03277729](https://clinicaltrials.gov/ct2/show/study/NCT03277729).

### **About Mustang Bio**

Mustang Bio, Inc. ("Mustang") 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](http://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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