October 27, 2022

Mustang Bio Announces Phase 1/2 Clinical Trial Data of MB-106, a First-in-Class CD20-targeted, Autologous CAR T Cell Therapy, to be Presented at 11th International Workshop for Waldenstrom's Macroglobulinemia

MB-106 demonstrated 100% overall response rate in Waldenstrom macroglobulinemia

Data to be presented by Fred Hutch's Dr. Mazyar Shadman

WORCESTER, Mass., Oct. 27, 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 results from the Waldenstrom macroglobulinemia ("WM") cohort and other interim data from the ongoing Phase 1/2 clinical trial of MB-106, a CD20-targeted, autologous CAR T cell therapy being conducted at Fred Hutchinson Cancer Center ("Fred Hutch"), will be presented at the 11th International Workshop for Waldenstrom's Macroglobulinemia ("IWWM-11") taking place in Madrid, Spain. MB-106 is being developed in a collaboration between Mustang and Fred Hutch to treat patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHLs") and chronic lymphocytic leukemia ("CLL").

Details of the presentation are as follows:

Title: CD20 CAR-T therapy for WM and other B-NHLs
Session: Session XVI - Novel Treatment Approaches to WM-Clinical III
Session Date and Time: Saturday, October 29, 2022, 14:00-15:00 Central European Summer Time
Presenter: Mazyar Shadman, M.D., M.P.H., Associate Professor and physician at Fred Hutch and University of Washington

"We are very pleased with the advancement of the MB-106 clinical program which includes the recently announced multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating its safety and efficacy, the first MB-106 clinical trial under Mustang's

Investigational New Drug Application. Additionally, we are grateful that the Fred Hutch team continues to present compelling data from its ongoing Phase 1/2 clinical trial that demonstrate high efficacy and a favorable safety profile across CLL and B-NHLs including WM, a rare form of this cancer," said Manuel Litchman, M.D., President and Chief Executive Officer of Mustang. "Finally, having been granted Orphan Drug Designation by the FDA for WM, we are looking forward to treating additional WM patients in the Mustang-sponsored Phase 1 portion of our trial in order to support a fast-to-market Phase 2 strategy for this indication."

As previously reported, highlights from the interim data of 28 patients treated in an ongoing Phase 1/2 clinical trial at Fred Hutch continue to support MB-106 as a viable CAR T cell therapy for B-NHLs and CLL. As of September 2022, the interim data show:

- An overall response rate ("ORR") of 96% and complete response ("CR") rate of 75% observed in a wide range of hematologic malignancies including follicular lymphoma ("FL"), CLL, diffuse large B-cell lymphoma ("DLBCL")
- A 100% ORR and CR in the two patients with WM
- Twelve patients have experienced CR for more than 12 months (10 ongoing); four patients with CR for more than two years and the longest patient with CR is at 33 months
- Six patients with partial response ("PR") improved to CR and all remain in ongoing CR
- All three patients previously treated with CD-19 CAR T cell therapy have responded to treatment
- A favorable safety profile for MB-106 as an outpatient therapy remains with no CRS or ICANS ≥ Grade 3
- CAR-T persistence results in deepening responses following initial 28-day assessments

For more information about IWWM-11, please click here.

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 Waldenstrom Macroglobulinemia
Waldenstrom macroglobulinemia ("WM"), also known as lymphoplasmacytic lymphoma, is a rare type of non-Hodgkin lymphoma ("NHL"), a malignant disorder of the bone marrow and lymphatic tissues. The proliferation of cancer cells can crowd out normal cells in these tissues, leading to low levels of red blood cells, white blood cells, and platelets which, in turn, causes fatigue, shortness of breath, infections, bruising, and bleeding. In addition, the cancer cells make large amounts of the large antibody protein immunoglobulin M, or IgM, which cause the blood to become thick. This hyperviscosity of the blood affects its flow through the smaller blood vessels, leading to some of the other manifestations of the disease, such as visual and neurological symptoms. WM is a rare disorder with an incidence of approximately 3 per million people per year, and 1,400 new cases are diagnosed in the U.S. each year. The median age at diagnosis is 70 years.

About the MB-106 Phase 1/2 clinical trial
The six-center Phase 1/2 clinical trial is a three-arm study targeting chronic lymphocytic leukemia ("CLL") and B-cell non-Hodgkin lymphomas ("B-NHL") including follicular lymphoma ("FL"), diffuse large B-cell lymphoma and mantle cell lymphoma and will enroll

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 that the U.S. Food and Drug Administration recently granted MB-106 Orphan Drug Designation to treat. Given the Mustang-IND clinical trial is using the same lentiviral vector as other clinical trials evaluating MB-106, the FDA has allowed dose escalation to begin at a higher dose than what was originally conducted at Fred Hutch.

An estimated 287 patients are anticipated to be enrolled in the trial. All patients must have evidence of CD20 expression in both phases of the clinical trial. In Phase 1, escalating MB-106 dose levels will be tested independently in each arm using a 3+3 design. Patients will be enrolled in one of three arms, based on their primary diagnosis.

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, prior to proceeding to the Phase 2 portion of the study for each respective arm, where a total of up to 71 patients will participate 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 NHL or CLL patients will be treated with MB-106 at the respective RP2D for each arm. Each arm will initially include up to 20 patients. Based on the results of the interim analysis, an additional 51 patients may be added to each of the arms.

Additional information about the trial can be found onclinicaltrials.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 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 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 these trials can be found at http://www.clinicaltrials.gov using the identifier NCT05360238 for the Mustang 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.

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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