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Mustang Bio Announces Updated Interim Phase 1/2 Data for MB-106, CD20-Targeted CAR T Therapy, in Patients with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia

Very favorable safety profile suitable for outpatient treatment, high complete response rate and strong durability observed, including patients with Waldenstrom macroglobulinemia and those who received prior CD19-directed CAR T therapy

Expect to dose first patient in multicenter clinical trial this quarter

Data presented at 2022 Tandem Meetings I Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR

WORCESTER, Mass., April 25, 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 updated interim data from the ongoing Phase 1/2 clinical trial of MB-106, a CD20-targeted, autologous CAR T cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas (“B-NHLs”) and chronic lymphocytic leukemia (“CLL”). MB-106 is being developed in a collaboration between Mustang and Fred Hutchinson Cancer Center (“Fred Hutch”).

The data, which were presented by Mazyar Shadman, M.D., M.P.H., Associate Professor and physician at Fred Hutch and University of Washington, at the 2022 Tandem Meetings I Transplantation & Cellular Therapy Meetings of the American Society of Transplantation and Cellular Therapy (“ASTCT”) and Center for International Blood & Marrow Transplant Research (“CIBMTR”), demonstrated high efficacy and a very favorable safety profile in all patients (n=25). Five dose levels were used during the study, and complete responses were observed at all dose levels. Durable responses were observed in a wide range of hematologic malignancies including follicular lymphoma (“FL”), CLL, diffuse large B-cell lymphoma (“DLBCL”), and Waldenstrom macroglobulinemia (“WM”). An overall response

rate (“ORR”) of 96% and complete response (“CR”) rate of 72% was observed in all patients across all dose levels. Additionally, two patients had been previously treated with CD19-directed CAR T therapy and subsequently relapsed, and both responded to treatment, one patient with FL with a CR and the other with DLBCL with a partial response.

CAR T expansion was observed across all dose levels. At the 28-day evaluation, a favorable safety profile was observed in all 25 patients. No patients experienced grade 3 or 4 cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome (“ICANS”), and none of the FL patients experienced ICANS of any grade (n=18).

“We are pleased that in this single institution study, we observed a favorable safety profile and a high rate of complete and durable responses, which make MB-106 suitable for outpatient treatment. Additionally, the responses from patients treated previously with CD19-directed CAR T cell therapy show the potential of MB-106 as an immunotherapy option for these patients. Enrollment in this study remains open to patients with CD20+ B-NHLs and CLL, including patients with prior CAR T treatment,” said Dr. Shadman.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “MB-106 continues to demonstrate highly promising clinical activity. In particular, the 100% response rates of WM patients as well as of NHL patients previously treated with CD19-directed CAR T cell therapy underscore the potential for MB-106 to treat these patient populations with high unmet needs. The possible outpatient administration of this therapy makes it potentially even more compelling. We are excited to advance our CD20-targeted CAR T cell therapy program with the launch of a 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 and plan to dose the first patient this quarter.”

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 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 to be initiated shortly 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 trial can be found at http://www.clinicaltrials.gov using the identifier NCT03277729.

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 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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