February 15, 2022

Mustang Bio Announces City of Hope MB-105 Prostate Stem Cell Antigen CAR T Data Selected for Presentation at the 2022 American Society of Clinical Oncology Genitourinary Cancers Symposium

WORCESTER, Mass., Feb. 15, 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 City of Hope Phase 1 clinical trial data on MB-105, a prostate stem cell antigen (“PSCA”) chimeric antigen receptor (“CAR”) T-cell therapy administered systemically to patients with PSCA-positive metastatic castration-resistant prostate cancer (“mCRPC”), has been selected for a poster presentation at the 2022 American Society of Clinical Oncology (“ASCO”) Genitourinary (“GU”) Cancers Symposium taking place February 17-19, 2022, both virtually and in San Francisco.

The primary objectives of the Phase 1 clinical trial are to define the dose limiting toxicity (“DLT”), identify a recommended Phase 2 dose and describe preliminary bioactivity and efficacy. To date, 12 patients have been treated at City of Hope, one of the largest cancer research and treatment organizations in the United States, with a median age of 68 (42-72). Dosing began at 100 million (“M”) cells without lymphodepletion chemotherapy, then lymphodepletion consisting of fludarabine and cyclophosphamide was added to 100M cells prior to dose escalation to a planned maximum of 600M cells. Three patients were treated at the 100M cell dose with no DLTs. In the 100M cells plus lymphodepletion dose level, two patients experienced DLT of grade 3 non-infective cystitis and fatigue. The protocol was amended to reduce the cyclophosphamide dose and to intensify the monitoring with early intervention for cystitis.

No DLT occurred in three patients treated in the modified lymphodepletion 100M cell cohort. Cytokine release syndrome occurred in four patients, none with higher than Grade 2. The Response Evaluation Criteria in Solid Tumors (“RECIST”) of the 12 patients included seven stable disease patients and five progressive disease patients. PSA declines (one >90%) were seen as well as radiographic improvement, though RECIST response was limited to stable disease by concurrent bone metastases. Correlative studies indicated bioactivity of PSCA CAR T-cells.

The results indicate that PSCA-CAR T-cell therapy is feasible in patients with mCRPC with DLT of cystitis, and show preliminary anti-tumor effect at a dose of 100M cells plus lymphodepletion. It was concluded that escalation up to the next dose level of 300M can proceed in the trial.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “The Phase 1 data to be presented by Dr. Dorff on behalf of the City of Hope team demonstrate the potential of Mustang’s MB-105 as a PSCA-targeted CAR T-cell therapy for prostate cancer. There is a potential to apply this therapy in other solid tumors that express PSCA. We remain encouraged by the ongoing progress of this trial as we develop our pipeline of cell therapy treatments for patients with cancers that are difficult to treat.”

Details of the presentation are as follows:

Title: Phase 1 study of PSCA-targeted chimeric antigen receptor (CAR) T cell therapy for metastatic castration resistant prostate cancer (mCRPC)
Abstract Number: 91
Dates and Times: Poster Session A: Prostate Cancer, February 17, 2022; 11:30 a.m. - 1:00 p.m.; 5:45 - 6:45 p.m.
Presenter: Tanya Dorff, M.D., City of Hope Associate Clinical Professor, Department of Medical Oncology & Experimental Therapeutics and Section Chief of City of Hope’s Genitourinary Disease Program

For more information, please visit the ASCO Genitourinary Cancers Symposiumwebsite.

About MB-105 (PSCA CAR T technology)
MB-105 was developed in the laboratory of Saul Priceman, Ph.D., assistant professor in City of Hope’s Department of Hematology & Hematopoietic Cell Transplantation and associate director of translational sciences in the T Cell Therapeutics Research Laboratory led by Stephen Forman, M.D., Director of City of Hope’s Hematologic Malignancies Research Institute and the Laboratory’s Director.

The Phase 1 clinical trial of MB-105 will continue to enroll up to 33 patients. Its primary endpoints are to define safety and optimal dosing of PSCA CAR T cells in treating patients with PSCA-positive mCRPC. Secondary endpoints include assessing the expansion and persistence of PSCA CAR T cells, the clinical response based on Prostate Cancer Working Group 3 (PCWG3) criteria, survival outcomes and serum cytokine profiles in peripheral blood pre- and post-therapy, as well as describing the PSCA expression level on tumor cells prior to CAR T cell infusion and the relationship it may have with disease response and associated toxicities. For more information on this Phase 1 trial, please visit www.clinicaltrials.gov using identifier NCT03873805.

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.

Company Contacts:
Jaclyn Jaffe and Bill Begien
Mustang Bio, Inc.
(781) 652-4500
ir@mustangbio.com

Investor Relations Contact:
Daniel Ferry
LifeSci Advisors, LLC
(617) 430-7576
daniel@lifesciadvisors.com

Media Relations Contact:
Tony Plohoros
6 Degrees
(908) 591-2839
tplohoros@6degreespr.com

Source: Mustang Bio, Inc.