

Mustang Bio Announces Interim Phase 1/2 Data for MB-106 in Patients with Relapsed or Refractory B-cell Non-Hodgkin Lymphoma

Data presented at the 62nd American Society of Hematology (ASH) Annual Meeting show extremely favorable safety profile and clinical activity

89% overall response rate and 44% complete response rate in patients treated with modified cell manufacturing process

Key opinion leader conference call on Wednesday, December 9, 2020, at 1 p.m. EST

WORCESTER, Mass., Dec. 07, 2020 (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 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 lymphoma ("NHL"). MB-106 is being developed in a collaboration between Mustang and Fred Hutchinson Cancer Research Center ("Fred Hutch").

The data presented in a poster session at the 62nd American Society of Hematology ("ASH") Annual Meeting by Mazyar Shadman, M.D., M.P.H., Associate Professor, Clinical Research Division of Fred Hutch, included safety data from both the original and modified cell manufacturing processes (n=16) and efficacy data from the modified process (n=9). Dose level 1 was 3.3 x 10⁵ CAR-T cells/kg, dose level 2 was 1 x 10⁶ CAR-T cells/kg, and dose level 3 was 3.3 x 10⁶ CAR-T cells/kg. At the 28-day evaluation, an extremely favorable safety profile was observed in all 16 patients, with no reported immune effector cell-associated neurotoxicity syndrome (any grade) and only two patients experiencing cytokine release syndrome, with one grade 3 occurrence – unexplained alkaline phosphatase elevation in the setting of fever in a patient treated prior to cell process modification. Additionally, an overall response rate (ORR) of 89% and complete response (CR) rate of 44% was observed in the nine patients who were treated with the modified process. In patients with follicular lymphoma (n=7), the ORR was 85% and CR was 57%.

Mazyar Shadman, M.D., M.P.H., commented, "We are very pleased to observe an extremely

favorable safety profile as well as complete and partial responses with the modified cell manufacturing process of MB-106, our third generation fully human CD20 targeted CAR T cell therapy for treatment of relapsed or refractory B-cell non-Hodgkin lymphoma. It is important to note that all complete responders continue to remain in remission as of the ASH presentation date."

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "The interim data presented by Dr. Shadman at ASH highlight the very favorable safety profile and compelling clinical activity MB-106 has demonstrated to date in patients with relapsed or refractory B-cell non-Hodgkin lymphoma. We are highly encouraged by the responses observed in patients who received treatment with the revised cell manufacturing process and look forward to the continued progression of this CD20-targeted CAR T cell therapy program."

Mustang plans to file an Investigational New Drug ("IND") application in the first quarter of 2021 to enable the initiation of a multicenter Phase 2 trial of MB-106. The ongoing Phase 1/2 trial continues to enroll eligible patients with CD20+ NHL and has recently been modified to include patients with chronic lymphocytic leukemia as well. For more information on this trial, please visit www.clinicaltrials.gov using the identifier NCT03277729.

Conference Call

On Wednesday, December 9, 2020, at 1 p.m. EST, Mustang will host a conference call with key opinion leaders Dr. Shadman and Dr. Brian Till, both of Fred Hutch, to discuss the MB-106 data and modified cell manufacturing process. The Mustang team will also provide a corporate update on the company's pipeline and future plans. Following the formal presentations, the Mustang team, along with Drs. Till and Shadman, will be available for questions. To register for the call, 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 for approximately 30 days following the call.

About B-cell Non-Hodgkin Lymphoma (NHL)

There are several forms of NHL, including follicular lymphoma, mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma and small lymphocytic lymphoma, which account collectively for about 45% of all cases of NHL. Most types of NHL are incurable with available therapies, except for allogenic hematopoietic stem cell transplant (allo-SCT). More than 70,000 new cases of B-cell NHL are diagnosed each year in the United States, and more than 19,000 patients die annually due to this group of diseases.

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 partner, Fred Hutchinson Cancer Research Center ("Fred Hutch"), in the laboratory of Oliver Press, M.D., Ph.D., and Brian Till, M.D., in the Clinical Research Division and exclusively licensed to Mustang Bio 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 B-cell non-Hodgkin lymphoma patients. 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 a lentiviral gene therapy for X-linked severe combined immunodeficiency (XSCID), also known as bubble boy disease. 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 forwardlooking statements contained in the Private Securities Litigation Reform Act of 1995.

Company Contacts:

Jaclyn Jaffe and William 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.