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

95% overall response rate, 65% complete response rate and favorable safety profile in patients treated with modified cell manufacturing process

Data presented at the 63rd American Society of Hematology (ASH) Annual Meeting

Key opinion leader conference call on Thursday, December 16, 2021, at 2:30 p.m. EST

WORCESTER, Mass., Dec. 13, 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 updated 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 Research Center ("Fred Hutch").

The data presented in a poster session at the 63rd American Society of Hematology Annual Meeting ("ASH2021") by Mazyar Shadman, M.D., M.P.H., Associate Professor, Clinical Research Division of Fred Hutch and a physician at Seattle Cancer Care Alliance, included efficacy and safety data from patients who were treated following a major cell manufacturing modification (n=20). Five dose levels were used during the study: 1 x 10^5, 3.3 x 10^5, 1 x 10^6, 3.3 x 10^6 and 1 x 10^7 cells/kg. Durable responses were observed in a wide range of hematologic malignancies including follicular lymphoma, diffuse large B-cell lymphoma, CLL, and Waldenstrom's macroglobulinemia. An overall response rate ("ORR") of 95% and complete response ("CR") rate of 65% was observed in all patients across all dose levels. In patients with follicular lymphoma (n=15), the ORR was 93% and the CR rate was 73%. Robust CAR-T expansion and persistence was also observed. At the 28-day evaluation, a favorable safety profile was observed in all 20 patients, with no patients experiencing grade 3 or 4 cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome.

Mazyar Shadman, M.D., M.P.H., commented, “We are extremely pleased with the ongoing favorable safety profile and complete and durable responses with the current manufacturing process of MB-106, our third generation fully human CD20-targeted CAR T cell therapy for a mostly outpatient treatment of a wide range of relapsed or refractory hematologic malignancies. Given its safety and efficacy, CD20-targeted CAR T cell therapy has potential as an adoptive immunotherapy that could be utilized instead of, or in sequence with, CD19 CAR T cell therapy. Enrollment for this study remains robust for patients with CD20+ B-NHLs and CLL, including patients with prior CAR T treatment.”

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “The updated data presented by Dr. Shadman at ASH2021 expand on the compelling clinical activity of MB-106 in patients with relapsed or refractory B-cell hematologic malignancies. We are enthusiastic about the responses observed and look forward to the continued advancement of our CD20-targeted CAR T cell therapy program. We expect to enroll the first patient under Mustang’s MB-106 investigational new drug trial for patients with B-NHLs and CLL early next year.”

Webinar

On Thursday, December 16, 2021, at 2:30 p.m. EST, Mustang will host a webinar with Dr. Shadman and colleague Brian Till, M.D., both of Fred Hutch and physicians at Seattle Cancer Care Alliance, to discuss the updated results from the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 CD20-targeted CAR T therapy for B-NHLs 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-NHLs 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 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 at Fred Hutch, 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-NHLs and CLL. Additional information on the trial can be found at http://www.clinicaltrials.gov using the identifier NCT03277729.

Note: 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 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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