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

Data presented at the European Hematology Association 2021 Virtual Congress show favorable safety profile and compelling clinical activity

93% overall response rate and 67% complete response rate in patients treated with modified cell manufacturing process

Key opinion leader webinar on Tuesday, June 15, 2021, at 1 p.m. ET


The data presented in an e-poster session at the European Hematology Association 2021 Virtual Congress (“EHA2021”) by Mazyar Shadman, M.D., M.P.H., Associate Professor, Clinical Research Division of Fred Hutch, included safety and efficacy data from the cell manufacturing process that was modified to combine the culture of CD4+ and CD8+ cells. In the 15 patients treated, the overall response rate (“ORR”) was 93% (14/15) with a complete response (“CR”) rate of 67% (10/15). In 11 patients with follicular lymphoma (“FL”), ORR and CR were 91% (10/11) and 82% (9/11), respectively. As of the time of the e-poster submission to EHA2021, all patients who achieved CR remained in remission. One patient with FL had an initial partial response with a later disease progression, had a spontaneous CR and remains in remission. The patient with CLL also had a CR and undetectable measurable residual disease in peripheral blood and bone marrow by flow cytometry ($10^{-4}$) (uMRD4) on day 28. CAR T persistence was seen in all dose levels (“DL”) and, while expansion was faster in higher DL, the levels were comparable by day 28.

From a safety profile perspective, cytokine release syndrome (“CRS”) occurred in 6 patients (40%): 3 patients with grade 1 and 3 patients with grade 2. Only 1 patient (6.5%) experienced grade 2 immune effector cell-associated neurotoxicity syndrome (“ICANS”) and none of the 11 patients with FL experienced ICANS of any grade. No grade 3 or higher CRS or ICANS were seen in any patient.

Dr. Shadman commented, “MB-106 continues to demonstrate a very favorable safety and efficacy profile, as well as sustained complete responses. This compelling clinical activity, including the complete remissions in 67% of the patients in the trial, demonstrates the potential of MB-106 as a viable CD20-targeted CAR T cell therapy.
We are pleased that all complete responders continue to remain in remission, and we continue to enroll all eligible CD20+ NHL and CLL patients into this trial.”

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “We are encouraged by the updated MB-106 safety and efficacy data presented by Dr. Shadman today. As reported last month, the FDA has accepted Mustang’s IND application to initiate a multicenter Phase 1/2 clinical trial investigating the safety, tolerability and efficacy of MB-106 for relapsed or refractory B-NHL and CLL. We look forward to commencing the trial later this year and further advancing MB-106 for patients with B-NHL and CLL who are in need of new treatment options.”

For more information on the clinical trial at Fred Hutch, please visit www.clinicaltrials.gov using the identifier NCT03277729.

**Webinar**

On Tuesday, June 15, 2021, at 1 p.m. ET, Mustang will host a webinar with Dr. Shadman and colleague Brian Till, M.D., both of Fred Hutch, to discuss the updated interim results from the ongoing Phase 1/2 clinical trial investigating the safety and efficacy of MB-106 CD20-targeted CAR T for B-NHL 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 Company recently announced that the U.S. Food and Drug Administration (“FDA”) accepted its IND to initiate a multicenter Phase 1/2 clinical trial investigating the safety, tolerability and efficacy of MB-106 for relapsed or refractory B-NHL 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](http://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, 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-NHL and CLL. Additional information on the trial can be found at [http://www.clinicaltrials.gov](http://www.clinicaltrials.gov) using the identifier NCT03277729.

**About Mustang Bio**

Mustang Bio, Inc. (“Mustang”) 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 XSCID. 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](http://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