December 11, 2023

Mustang Bio Presents Updated Phase 1/2 Multicenter Clinical Data for MB-106 at the 2023 American Society of Hematology (ASH) Annual Meeting

Data showed favorable safety profile, complete response rate and durability in the treatment of patients with relapsed or refractory indolent B-cell Non-Hodgkin Lymphoma

100% of patients with follicular lymphoma achieved a complete response; no occurrence of CRS above grade 1 and no ICANS of any grade

Complete responses observed in patients previously treated with CD19-targeted CAR T-cell therapy

Outpatient administration found to be feasible

WORCESTER, Mass., Dec. 11, 2023 (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 difficult-to-treat cancers and rare genetic diseases, today announced updated encouraging safety and efficacy data from Mustang's multicenter Phase 1/2 clinical trial of MB-106, a CD20-targeted, 3rd-generation autologous CAR T-cell therapy for patients with relapsed or refractory B-cell non-Hodgkin lymphomas ("NHL") and chronic lymphocytic leukemia ("CLL"). The data were presented during a poster session on December 9th (Abstract #2102) at the 65th American Society of Hematology ("ASH") Annual Meeting and build upon previously reported data from a single-institution Phase 1/2 clinical trial conducted at Fred Hutchinson Cancer Center ("Fred Hutch"). MB-106 is being developed in a collaboration between Mustang and Fred Hutch.

"All nine patients have responded clinically to treatment in this multicenter trial and the safety and efficacy profile of MB-106 appears to be consistent with the original single-institution trial. It is especially encouraging that complete responses were observed in all patients with follicular lymphoma in this multicenter trial," said Mazyar Shadman, M.D., M.P.H., Study Chair, Innovators Network Endowed Chair at Fred Hutch, Associate Professor and physician at Fred Hutch and University of Washington. "One patient with follicular lymphoma who had six prior treatments including CD19-targeted CAR T-cell therapy experienced a complete response for the first time with no cytokine release syndrome (CRS) or immune effector cell-

associated neurotoxicity syndrome (ICANS)."

Highlights from the data include:

- All patients responded clinically to treatment with MB-106 (n=9); 100% overall response rate for patients with follicular lymphoma ("FL") and Waldenstrom macroglobulinemia ("WM")
- 100% of patients with FL (n=5) had a complete response; 1 very good partial response and 2 partial responses were observed in WM patients (n=3); and the hairy cell leukemia variant ("HCL-v") patient experienced stable disease, with prolonged, ongoing independence from blood transfusions
- Complete responses observed in patients previously treated with CD19-targeted CAR T-cell therapy
- MB-106 has a tolerable safety profile in patients with indolent NHL, with no occurrence of CRS above grade 1, and no ICANS of any grade, despite not using prophylactic tocilizumab or dexamethasone
- Outpatient administration was allowed and found to be feasible
- MB-106 CAR T-cell expansion and persistence in patients was demonstrated

Efficacy (combined results for dose level 1 & 2)

Best Responsesto Date[1]	**Follicular Lymphoma (n=5)**	**Waldenstrom Macroglobulinemia (n=3)**
Overall response rate (ORR),[2] n (%)	5 (100%)	3 (100%)
Complete response (CR), n (%)	5 (100%)	0
Very good partial response (VGPR),[3] n (%)	N/A	1 (33%)
Partial response (PR), n (%)	0	2 (67%)
Minor response,[3] n (%)	N/A	0
Stable disease (SD)	0	0

1. In WM patients, responses are evaluated using the 11th International Workshop on WM (IWWM) criteria (Treon, 2023). In lymphoma patients, PET-CT-based responses are evaluated using the Lugano Classification (Cheson, 2014).
2. ORR is the rate of PR or better in follicular lymphoma. ORR is the rate of minor response or better in WM.
3. VGPR and minor response are WM-specific response categories.
   N/A = Not applicable

Safety
CRS and ICANS (combined results for dose level 1 & 2)

	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
CRS, n (%)	5 (56%)	0	0	0
ICANS	0	0	0	0

- CRS = Cytokine release syndrome

- ICANS = Immune effector cell-associated neurotoxicity syndrome
- No related serious adverse events (SAEs) reported, apart from Grade 1 CRS.
- No prophylactic tocilizumab or dexamethasone was administered.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “Given the favorable data presented from the multicenter Mustang trial at ASH and from the original single-institutional Fred Hutch trial, we anticipate finalizing a recommended Phase 2 dose level in early 2024 and moving ahead with the first ever registrational CAR-T trial focused on relapsed or refractory WM. As we plan for an End-of-Phase 1 meeting with the FDA in the first half of 2024 to solicit approval for the design of this trial, we are especially encouraged by the safety of the higher dose level of 1.0×10^7 CAR T-cells/kg which so far is indistinguishable from the safety of the lower dose level and which we have manufactured successfully for all 5 patients enrolled to date at the higher dose level. Following that meeting, we anticipate initiating a trial enrolling 58 patients across 20 sites in North America, with top-line data expected as early as mid-2026.”

The data reported on nine patients from the indolent lymphoma arm of the multicenter clinical trial, including five patients with follicular lymphoma, three patients with Waldenstrom macroglobulinemia, and one patient with transfusion-dependent hairy cell leukemia variant. The patients had been treated with a median of 4 lines of prior therapy (range: 1-9), including 2 patients who had received prior CD19-directed CAR T-cell therapy and 1 patient who had received prior autologous stem cell transplant. The patients received one of two dose levels: dose level 1, 3.3×10^6 CAR T-cells/kg body weight, or dose level 2, 1.0×10^7 CAR T-cells/kg.

A link to the poster can be found on the Publications page of the Mustang Bio website here.

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 difficult-to-treat cancers 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’s common stock is registered under the Securities Exchange Act of 1934, as amended, and Mustang 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 contains “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, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions. The

Company's forward-looking statements, include, but are not limited to, any statements relating to our growth strategy and product development programs, including the timing of and our ability to make regulatory filings such as INDs and other applications and to obtain regulatory approvals for our product candidates, statements concerning the potential of therapies and product candidates and any other statements that are not historical facts. Actual events or results may differ materially from those described in this press release due to a number of risks and uncertainties. Risks and uncertainties include, among other things, risks related to the satisfaction of the conditions necessary to transfer the lease of the Company's manufacturing facility and receive the contingent payment in connection with the Company's sale of its manufacturing facility in the anticipated timeframe or at all; whether the purchaser of the Company's manufacturing facility is able to successfully perform its obligation to produce the Company's products under the manufacturing services agreement on a timely basis and to acceptable standards; disruption from the sale of the Company's manufacturing facility making it more difficult to maintain business and operational relationships; negative effects of the announcement or the consummation of the transaction on the market price of the Company's common stock; significant transaction costs; the development stage of the Company's primary product candidates, 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 Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K filed on March 30, 2023, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. 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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