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Mustang Bio Announces First Patient Treated in Its Multicenter Phase 1/2 Clinical Trial of MB-106, a First-in-Class CD20-targeted, Autologous CAR T Cell Therapy to Treat B-cell Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia

Enrollment continues in clinical trial of MB-106 under Mustang's IND; next data disclosure anticipated 4Q 2022

Ongoing clinical trial of MB-106 at Fred Hutch continues to demonstrate high efficacy, durable responses, and favorable safety profile across wide range of hematologic malignancies

WORCESTER, Mass., Oct. 06, 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 the first patient has been treated in its multicenter, open-label, non-randomized Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106, Mustang's first-in-class CD20-targeted, autologous CAR T cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphomas ("B-NHL") and chronic lymphocytic leukemia ("CLL"). The patient did not experience cytokine release syndrome ("CRS") or immune effector cell-associated neurotoxicity syndrome ("ICANS"). MB-106 is being developed in a collaboration between Mustang and Fred Hutchinson Cancer Center ("Fred Hutch"). The multicenter trial under Mustang's Investigational New Drug Application ("IND") builds upon the initial, ongoing Phase 1/2 clinical trial taking place at Fred Hutch in a single-center study under Fred Hutch's IND.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang said, "The first clinical trial under Mustang's IND is an important milestone in the ongoing development and evaluation of MB-106. Data presented at several prestigious medical meetings earlier this year from the initial, ongoing Phase 1/2 clinical trial at Fred Hutch show that MB-106 continues to demonstrate high efficacy and a favorable safety profile across patients with a

wide range of hematologic malignancies. We look forward to providing updates on our multicenter MB-106 clinical trial as it progresses and anticipate reporting efficacy data in the fourth quarter of this year."

Interim data from 28 patients treated in the initial, ongoing Phase 1/2 investigator-sponsored clinical trial at Fred Hutch continue to support MB-106 as a viable CAR T cell therapy for B-NHLs and CLL. As of September 9, 2022, the interim data show:

- An overall response rate of 96% and complete response ("CR") rate of 75% in a wide range of hematologic malignancies including follicular lymphoma ("FL"), CLL, diffuse large B-cell lymphoma, and Waldenstrom macroglobulinemia
- Twelve patients have experienced CR for more than 12 months (10 ongoing); four patients with CR for more than two years and the longest patient with CR is at 33 months
- Six patients with partial response ("PR") improved to CR and all remain in ongoing CR
- All three patients previously treated with CD19 CAR T cell therapy have responded to treatment with MB-106
- A favorable safety profile for MB-106 as an outpatient therapy remains with no CRS or ICANS ≥ Grade 3
- CAR-T persistence results in deepening responses following initial 28-day assessments

"We are excited to broaden the evaluation of MB-106 with this multicenter clinical trial under Mustang's IND. To date, the data from the initial, ongoing clinical trial at Fred Hutch continue to demonstrate a high rate of complete and durable responses," said Mazyar Shadman, M.D., M.P.H., Study Chair, Associate Professor and physician at Fred Hutch and University of Washington. "In addition, MB-106 has shown potential to treat patients in an outpatient setting and provide another immunotherapy option for patients treated previously with CD19-directed CAR T cell therapy."

About Mustang's Multicenter MB-106 Phase 1/2 clinical trial

The six-center Phase 1/2 clinical trial is a three-arm study targeting CLL and B-NHL including FL, diffuse large B-cell lymphoma and mantle cell lymphoma. Included in the eligibility criteria are patients who have relapsed after treatment with CD19 CAR-T cell therapy. Additionally, the FL arm will evaluate other indolent histologies including Waldenstrom macroglobulinemia, a rare type of B-NHL for which the U.S. Food and Drug Administration recently granted MB-106 Orphan Drug Designation. Since the Mustang-sponsored multicenter clinical trial is using the same lentiviral vector as the Fred Hutch-sponsored single-center trial, the FDA has allowed dose escalation to begin at a higher dose than what was originally conducted at Fred Hutch.

An estimated 287 patients are anticipated to be enrolled in the trial. All patients must have evidence of CD20 expression in both phases of the clinical trial. In Phase 1, escalating MB-106 dose levels will be tested independently in each arm using a 3+3 design. Patients will be enrolled in one of three arms, based on their primary diagnosis.

A total of up to 18 patients are anticipated to be treated in each Phase 1 arm, including six patients at the maximum tolerated dose, prior to proceeding to the Phase 2 portion of the study for each respective arm, where a total of up to 71 patients will participate in each independent arm. Safety of each dose level will be reviewed for each arm until the maximum

tolerated dose has been reached and the recommended Phase 2 dose ("RP2D") has been established for each arm. An assessment of the safety and tolerability of the dose will be made by the Safety Review Committee based on the data from the 28-day dose-limiting toxicity observation period.

In Phase 2, specific arms of relapsed or refractory CD20-positive B-cell NHL or CLL patients will be treated with MB-106 at the respective RP2D for each arm. Each arm will initially include up to 20 patients. Based on the results of the interim analysis, up to an additional 51 patients may be added to each of the arms.

Additional information about the trial can be found on clinicaltrials.gov using the identifier NCT05360238.

About MB-106 (CD20-targeted autologous 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 was exclusively licensed to Mustang in 2017. The lentiviral vector drug substance used to transduce patients' cells to create the MB-106 drug product produced at Fred Hutch has been optimized as a third-generation CAR derived from a fully human antibody. MB-106 is currently in a Phase 1/2 open-label, dose-escalation trial at Fred Hutch in patients with B-NHLs and CLL. The same lentiviral vector drug substance produced at Fred Hutch will be used to transduce patients' cells to create the MB-106 drug product produced at Mustang Bio's Worcester, MA, cell processing facility for administration in the multicenter Phase 1/2 clinical trial under Mustang Bio's IND. It should be noted that Mustang Bio has introduced minor improvements to its cell processing to facilitate eventual commercial launch of the product. In addition, prior to commercial launch, Mustang Bio will replace the Fred Hutch lentiviral vector drug substance with vector produced at a commercial manufacturer. Additional information on these trials can be found at http://www.clinicaltrials.gov using the identifier NCT05360238 for the Mustang multicenter trial and NCT03277729 for the ongoing trial at Fred Hutch.

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 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, 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. 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 Part I, Item 1A, “Risk Factors,” in our Annual Report on Form 10-K filed on March 23, 2022, 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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