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Mustang Bio Announces Orphan Drug Designation Granted to MB-106, a CD20-targeted, Autologous CAR T Cell Therapy for the Treatment of Waldenstrom Macroglobulinemia

Multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL under Mustang's IND now open to enrollment

WORCESTER, Mass., June 22, 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 U.S. Food and Drug Administration ("FDA") has granted Orphan Drug Designation to MB-106, Mustang's CD20-targeted, autologous CAR T cell therapy for the treatment of Waldenstrom macroglobulinemia ("WM" or "Waldenstrom"), a rare type of B-cell non-Hodgkin lymphoma ("B-NHL"). MB-106 is being developed in a collaboration between Mustang and Fred Hutchinson Cancer Center ("Fred Hutch") to treat patients with relapsed or refractory B-NHLs and chronic lymphocytic leukemia ("CLL").

The FDA grants Orphan Drug Designation to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it has Orphan Drug designation, which is independent from intellectual property protection.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We are very pleased to receive Orphan Drug Designation from the FDA, as it is an important regulatory milestone for Mustang's MB-106 program for the treatment of Waldenstrom macroglobulinemia, a rare B-NHL with a significant unmet medical need. We look forward to dosing the first patient in our multicenter Phase 1/2 clinical trial evaluating the safety and efficacy of MB-106 for relapsed or refractory B-NHL and CLL under Mustang's IND shortly.

In the Phase 1 portion of this trial, MB-106 dose escalation will proceed in three separate arms, and Waldenstrom patients will be included in the indolent lymphoma arm in parallel with accrual of patients to the aggressive lymphoma and CLL arms."

MB-106 data presented earlier this month at the European Hematology Association 2022 Hybrid Congress continue to demonstrate high efficacy and a very favorable safety profile across all five dose levels. The overall response ("ORR") was 96% across all dose levels and all indications (n=26). In particular, the 100% complete response rates by PET scan of patients with WM (n=2) as well as of patients with B-NHL previously treated with CD19-directed CAR T cell therapy (n=2) underscore the potential for MB-106 to treat these patient populations with high unmet needs. Durable responses were observed in a wide range of hematologic malignancies including follicular lymphoma, CLL, diffuse large B-cell lymphoma and WM. The possible outpatient administration of this therapy makes it potentially even more compelling. Currently no CAR T therapy is specifically approved for WM.

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 Waldenstrom Macroglobulinemia
Waldenstrom macroglobulinemia ("WM"), also known as lymphoplasmacytic lymphoma, is a rare type of non-Hodgkin lymphoma ("NHL"), a malignant disorder of the bone marrow and lymphatic tissues. The proliferation of cancer cells can crowd out normal cells in these tissues, leading to low levels of red blood cells, white blood cells, and platelets which, in turn, causes fatigue, shortness of breath, infections, bruising, and bleeding. In addition, the cancer cells make large amounts of the large antibody protein immunoglobulin M, or IgM, which cause the blood to become thick. This hyperviscosity of the blood affects its flow through the smaller blood vessels, leading to some of the other manifestations of the disease, such as visual and neurological symptoms. WM is a rare disorder with an incidence of approximately 3 per million people per year, and 1,400 new cases are diagnosed in the U.S. each year. The median age at diagnosis is 70 years.

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 that is now open to enrollment 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 out license 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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