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Mustang Bio Announces FDA Acceptance of IND Application for MB-106, a CD20-Targeted CAR T Therapy

The Phase 1/2 multicenter study to assess the safety, tolerability and efficacy of MB-106 in patients with relapsed or refractory CD20+ B-cell non-Hodgkin lymphoma and chronic lymphocytic leukemia is expected to begin enrolling patients in the third quarter of this year

WORCESTER, Mass., May 10, 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 that the U.S. Food and Drug Administration (“FDA”) has accepted the Company’s Investigational New Drug (“IND”) application to initiate a Phase 1/2 multicenter study to assess the safety, tolerability and efficacy of MB-106, a CD20-targeted CAR T therapy for relapsed or refractory CD20+ B-cell non-Hodgkin lymphoma (“B-NHL”) and chronic lymphocytic leukemia (“CLL”).

MB-106 targets CD20, a commercially validated target on the surface of cancer cells that has lacked a strong CAR T-based clinical focus in the U.S. MB-106 cells express a third-generation CAR derived from a fully human antibody that originated in the Fred Hutchinson Cancer Research Center (“Fred Hutch”) laboratories of the late Oliver Press, M.D., Ph.D., and Brian Till, M.D., Associate Professor in the Clinical Research Division. The CAR T therapy was exclusively licensed to Mustang in 2017, and Fred Hutch and Mustang collaborated to develop the cell processing that will be used in the Mustang IND Phase 1/2 clinical trial.

To date, the same vector planned for use in the manufacturing of MB-106 is currently being evaluated in the ongoing Phase 1/2 study sponsored by Fred Hutch, where Mazyar Shadman, M.D., M.P.H., Associate Professor in the Clinical Research Division, is the Principal investigator. Data from this ongoing study were presented by Dr. Shadman at the 62nd Annual American Society of Hematology meeting in 2020 and demonstrated a favorable safety profile, with an 89% overall response rate (ORR; 8/9 patients) and a 44% complete response rate (CR; 4/9 patients).

NHL is one of the most common cancers in the United States, accounting for about 4% of all cancers, and CLL accounts for about one-third of the new cases of leukemia. The American Cancer Society estimates that in the U.S. in 2021 about 81,560 people will be diagnosed

NHL and 21,250 with CLL.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “We are pleased with the FDA’s acceptance of our IND application for MB-106, which allows us to further advance this CAR T therapy as a potentially safe and effective treatment option for B-NHL and CLL. It is especially gratifying that we were able to achieve this milestone in just 28 days after our IND submission. We are committed to finding better treatment options for patients living with these cancers and look forward to initiating our multicenter, Phase 1/2 clinical trial later this year, with Dr. Shadman as the Study Chair.”

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.

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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