FDA Clears IND for Mustang Bio's MB-102 (CD123 CAR T)

New York, NY – August 5, 2019 – 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 approved the Company's Investigational New Drug (IND) application to initiate a multi-center Phase 1/2 clinical trial of MB-102 (CD123 CAR T) in acute myeloid leukemia (AML), blastic plasmacytoid dendritic cell neoplasm (BPDCN) and high-risk myelodysplastic syndrome (MDS).

MB-102 is a CAR T cell therapy that is produced by engineering patient T cells to recognize and eliminate CD123-expressing tumors. CD123 is widely expressed on bone marrow cells of patients with myelodysplastic syndrome and hematologic malignancies, including in 75-89% of AML patients and over 90% in BPDCN patients. MB-102 has shown promising response rates in early small populations of these patients in an investigator-sponsored Phase 1 clinical trial being conducted by City of Hope, where the CAR T cell therapy was also developed.

According to the American Cancer Society, there were an estimated 19,520 new U.S. cases of AML in 2018 and the disease has an estimated five-year survival rate of 25%. In 2016, an American Society of Hematology Education Program article reported that there are about 700 new BPDCN cases in the U.S. and 1,000 in Europe per year, with a median survival of 12 to 14 months.

On July 24, 2019, Mustang announced that the FDA granted Orphan Drug Designation to MB-102 for the treatment of AML. The FDA also previously granted Orphan Drug Designation to MB-102 for the treatment of BPDCN.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "The FDA's approval of our IND application for MB-102 marks a significant milestone for Mustang, as this is our first IND. We are excited to initiate our multi-center Phase 1/2 clinical trial later in 2019 and process patient cells in our manufacturing facility, which opened in June 2018. We are passionate about meeting the needs of patients living with AML, BPDCN and MDS and look forward to further developing MB-102 to help address these devastating diseases."

About MB-102 (CD123 CAR T)

MB-102 (CD123 CAR T) is a CAR T cell therapy that is produced by engineering patient T cells to recognize and eliminate CD123-expressing tumors. CD123 is widely expressed on bone marrow cells of patients with myelodysplastic syndromes, as well as in hematologic malignancies, including AML, B-cell acute lymphoblastic leukemia, hairy cell leukemia, BPDCN, chronic myeloid leukemia and Hodgkin's lymphoma.

In the first-in-human clinical trial at City of Hope (NCT02159495), MB-102 has demonstrated complete responses at low doses in AML and BPDCN without dose-limiting toxicities, as reported at the American Society of Hematology (ASH) Annual Meeting in December 2017 and the American Association for Cancer Research (AACR) Special Conference on Tumor Immunology and Immunotherapy in November 2018. Dose escalation continues at City of Hope in both indications. MB-102 has received Orphan Drug Designation from the U.S. Food and Drug Administration for AML and BPDCN.

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 and CRISPR/Cas9-enhanced 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. 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.

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