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Mustang Bio Receives European Medicines Agency PRIME Designation for MB-107 to Treat X-Linked Severe Combined Immunodeficiency in Newly Diagnosed Infants

WORCESTER, Mass., Aug. 02, 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 European Medicines Agency ("EMA") has granted Priority Medicines ("PRIME") designation to MB-107, its lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID") in newly diagnosed infants, also known as bubble boy disease.

In addition to PRIME designation, the EMA granted Advanced Therapy Medicinal Product ("ATMP") classification to MB-107 in April 2020 and Orphan Drug designation in November 2020. MB-107 has also received Orphan Drug, Rare Pediatric Disease and Regenerative Medicine Advanced Therapy ("RMAT") designations from the U.S. Food and Drug Administration ("FDA").

"We are very pleased that the EMA continues to acknowledge the potential for MB-107 to be a new treatment option for patients with XSCID, a devastating rare disease," said Manuel Litchman, M.D., President and Chief Executive Officer of Mustang. "Receiving PRIME designation is an exciting milestone for Mustang as we prepare to initiate a pivotal, multicenter Phase 2 clinical trial of MB-107 in newly diagnosed patients with XSCID at the end of this quarter. We look forward to having a kick-off meeting with the Committee on Advanced Therapies and its multidisciplinary group of experts to provide additional guidance on our overall MB-107 development plan and regulatory strategy to potentially further expedite clinical development and approval in Europe."

The PRIME program aims to optimize development plans and speed up evaluation of promising medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options. To be eligible and accepted for PRIME deisgnation, a treatment has to demonstrate the potential to benefit patients with unmet medical needs based on early clinical data. Through the PRIME program, the EMA offers enhanced interactions and early dialogue, including the appointment of a Committee on

Advanced Therapies ("CAT") rapporteur, to help build knowledge ahead of a Marketing Authorization Application ("MAA"). It also provides a pathway for accelerated assessment of an MAA under the centralized procedure so that these medicines may reach patients as early as possible. For more information on the PRIME program visit the EMA website.

The same lentiviral vector used in MB-107 is currently being assessed in an ongoing Phase 1/2 clinical trial for XSCID in newly diagnosed infants under 2 years of age at St. Jude Children's Research Hospital ("St. Jude"), UCSF Benioff Children's Hospital and Seattle Children's Hospital. Additionally, it is being assessed in a Phase 1/2 clinical trial at the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health, for XSCID patients who have been previously treated with hematopoietic stem cell transplantation ("HSCT") and for whom re-treatment is indicated.

About X-linked Severe Combined Immunodeficiency ("XSCID")
X-linked severe combined immunodeficiency is a rare genetic disorder that occurs in approximately 1 per 225,000 births. It is characterized by the absence or lack of function of key immune cells, resulting in a severely compromised immune system and death by 1 year of age if untreated. Patients with XSCID have no T-cells or natural killer (NK)-cells. Although their B-cells are normal in number, they are not functional. As a result, XSCID patients are usually affected by severe bacterial, viral or fungal infections early in life and often present with interstitial lung disease, chronic diarrhea and failure to thrive. Among patients who receive HSCT, many are unable to establish adequate T-cell immunity or lose T-cell immunity over time. Further, approximately two-thirds of patients who receive HSCT lack sufficient B-cell immunity and need lifelong immunoglobulin replacement therapy.

The specific genetic disorder that causes XSCID is a mutation in the gene coding for the common gamma chain (γ_c), a protein that is shared by the receptors for at least six interleukins. These interleukins and their receptors are critical for the development and differentiation of immune cells. The gene coding for γ_c is known as IL-2 receptor gamma, or *IL2RG*. Because *IL2RG* is located on the X-chromosome, XSCID is inherited in an X-linked recessive pattern, resulting in almost all patients being male.

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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