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Mustang Bio Receives Advanced Therapy Medicinal Product Classification from European Medicines Agency for MB-107 Lentiviral Gene Therapy for X-Linked Severe Combined Immunodeficiency

NEW YORK, April 20, 2020 (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 Advanced Therapy Medicinal Product ("ATMP") classification to MB-107, Mustang's lentiviral gene therapy for the treatment of X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease. The U.S. Food and Drug Administration ("FDA") previously granted Regenerative Medicine Advanced Therapy ("RMAT") designation to MB-107 for the treatment of XSCID in August 2019.

EMA grants ATMP classifications to new therapeutics that are based on genes or cells and intended as long-term or permanent therapeutic solutions to acute or chronic human diseases at a genetic, cellular or tissue level. The ATMP program provides specific regulatory guidelines for preclinical development, manufacturing and product quality testing of ATMPs and offers incentives, including fee reductions for regulatory advice, recommendations and evaluation and certification of quality and non-clinical data.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "We are extremely encouraged that the EMA has granted MB-107 with ATMP classification, an important step in establishing our path to market approval and commercialization in Europe. This classification complements the RMAT designation we received last year from the FDA and brings us closer to realizing our goal of commercializing MB-107 for XSCID patients, as these patients are in desperate need of innovative and potentially curative treatment options."

MB-107 is currently being assessed in two Phase 1/2 clinical trials for XSCID: the first in newly diagnosed infants under the age of two at St. Jude Children's Research Hospital ("St. Jude"), UCSF Benioff Children's Hospital in San Francisco and Seattle Children's Hospital and the second in patients over the age of two who have received prior hematopoietic stem

cell transplantation at the National Institutes of Health. Under a licensing partnership with St. Jude, Mustang intends to develop the lentiviral gene therapy for commercial use as MB-107.

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. 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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