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Mustang Bio Announces Initial Phase 1 Data on MB-105 for Patients with PSCA-positive Castration Resistant Prostate Cancer

Data presented by City of Hope at 27th Annual Prostate Cancer Foundation Scientific Retreat

WORCESTER, Mass., Oct. 26, 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 one patient‘s experience on the Phase 1 trial of MB-105, a prostate stem cell antigen (PSCA) chimeric antigen receptor (CAR) T administered systemically to patients with PSCA-positive metastatic castration-resistant prostate cancer (mCRPC), was presented at the virtual 27th Annual Prostate Cancer Foundation Scientific Retreat.

Tanya Dorff, M.D., City of Hope Associate Clinical Professor, Department of Medical Oncology & Experimental Therapeutics and Head of its Genitourinary Cancer Program and the trial’s principal investigator, presented a description of the correlative science from the ongoing Phase 1 open-label clinical trial of MB-105, one of the first CAR T trials for prostate cancer in the nation. In a 73-year-old male patient with PSCA-positive mCRPC who was treated with MB-105 and lymphodepletion (a standard CAR T pre-conditioning regimen) after failing eight prior therapies, MB-105 demonstrated on day 28 a 94 percent reduction in prostate-specific antigen (PSA), near complete reduction of measurable soft tissue metastasis by computerized tomography, and improvement in bone metastases by magnetic resonance imaging. The therapy was associated with cytokine release syndrome, which was clinically managed with tocilizumab (anti-IL-6 receptor antibody), and hemorrhagic cystitis requiring transfusion which clinically resolved in 30 days.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “We are encouraged by the initial data presented by City of Hope from the ongoing Phase 1 trial of Mustang’s CAR T cell therapy MB-105. We see potential for this PSCA-targeted CAR T in the treatment of prostate cancer, as well as other difficult-to-treat solid tumor cancers. We look forward to the continued progression of this trial and anticipate providing further data in the second half of 2021.”

According to the American Cancer Society (ACS), prostate cancer is the most common cancer in American men, excluding skin cancer. ACS estimates 191,930 new cases of prostate cancer in the U.S. will be diagnosed this year, and roughly one out of every nine men will be diagnosed with prostate cancer during his lifetime. The median survival for men with CRPC is less than two years, according to the American Urological Association.

About MB-105 (PSCA CAR T technology)
MB-105 was developed in the laboratory of Saul Priceman, Ph.D., assistant professor in City of Hope's Department of Hematology & Hematopoietic Cell Transplantation and associate director of translational sciences in the T Cell Therapeutics Research Laboratory led by Stephen Forman, M.D., leader of City of Hope's Hematologic Malignancies and Stem Cell Transplantation Institute and the laboratory's director.

The Phase 1 clinical trial of MB-105 will continue to enroll up to 33 patients. Its primary endpoints are to define safety and optimal dosing of PSCA CAR T cells in treating patients with PSCA-positive mCRPC. Secondary endpoints include assessing the expansion and persistence of PSCA CAR T cells, the clinical response based on Prostate Cancer Working Group 3 (PCWG3) criteria, survival outcomes and serum cytokine profiles in peripheral blood pre- and post-therapy, as well as describing the PSCA expression level on tumor cells prior to CAR T cell infusion and the relationship it may have with disease response and associated toxicities. For more information on this Phase 1 trial, please visit www.clinicaltrials.gov using identifier NCT03873805.

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 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 the treatment of X-linked severe combined immunodeficiency (XSCID), also known as bubble boy disease. 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, 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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