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## **Mustang Bio and City of Hope Announce First Patient Dosed in Phase 1 Clinical Trial of MB-101 (IL13R $\alpha$ 2-specific CAR T cells) to Treat Leptomeningeal Brain Tumors**

**First dose occurred in trial underway at City of Hope to evaluate safety and feasibility of administering therapy in patients with brain tumors such as glioblastoma, ependymoma or medulloblastoma**

WORCESTER, Mass. and DUARTE, Calif., May 18, 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, and [City of Hope](#), a world-renowned independent cancer research and treatment center, today announced that the first patient has been dosed in a clinical trial to establish the safety and feasibility of administering MB-101 (autologous IL13R $\alpha$ 2-CAR T cells) to patients with leptomeningeal brain tumors (e.g., glioblastoma, ependymoma or medulloblastoma). The trial will enroll up to 30 patients and is taking place at City of Hope, where this [chimeric antigen receptor T \("CAR T"\) cell therapy](#) was initially developed. Even though it is a single center clinical trial, Mustang and City of Hope will facilitate patient transfers from other centers, as needed.

All subjects enrolled in the Phase 1 single-center, two-arm clinical trial will undergo surgery for the placement of an intraventricular (ICV) Rickham catheter for CAR T cell delivery. The Phase 1 trial will determine the safety and feasibility of administering MB-101 through the ICV Rickham catheter over four weekly cycles in patients with glioblastoma (Arm 1) and ependymoma or medulloblastoma (Arm 2). The primary endpoints that will be evaluated are toxicity and survival at three months. Secondary endpoints include overall survival, CAR T and endogenous T cell levels, cytokine levels and phenotype detection in peripheral blood, tumor cyst fluid and cerebrospinal fluid.

[Lisa Feldman](#), M.D., Ph.D., a neurosurgeon and assistant clinical professor in the Division of Neurosurgery at City of Hope and principal investigator of the clinical trial, commented, "Based on our research to date, including a previous clinical trial at City of Hope, further evaluation is warranted for this CAR T cell therapy. The prior clinical trial demonstrated

encouraging potential of administering autologous IL13R $\alpha$ 2-CAR T cells intraventricularly to help treat patients with leptomeningeal brain tumors, a form of metastatic brain cancer that is difficult to treat. We continue to work closely with the Mustang team to potentially bring a safe, effective treatment option to patients suffering with this life-threatening disease.”

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, “The successful dosing of the first patient in this clinical trial of MB-101 is an important milestone in Mustang’s development program. We are pleased to support City of Hope to further study MB-101 in leptomeningeal brain tumors to potentially bring hope to patients suffering from this devastating and fatal disease. MB-101 has already demonstrated therapeutic potential when infused into the ventricular system, including delivering a complete response in a patient with leptomeningeal glioblastoma that was published in the *New England Journal of Medicine*. We aim to generate additional data that supports the advancement of this program.”

Additional information about the trial can be found on [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04661384) using the identifier [NCT04661384](https://clinicaltrials.gov/ct2/show/study/NCT04661384).

#### **About MB-101 (IL13R $\alpha$ 2-specific CAR T cells)**

IL13R $\alpha$ 2 is an attractive target for CAR T therapy as it has limited expression in normal tissue but is overexpressed on the surface of the majority of malignant glioma cells, including glioblastoma multiforme, ependymoma and medulloblastoma. CAR T cells are designed to express a membrane-tethered IL-13 receptor ligand (IL-13) incorporating a single-point mutation that provides high affinity for IL13R $\alpha$ 2 and reduces binding to IL13R $\alpha$ 1 in order to reduce healthy tissue targeting. Mustang is developing MB-101 as an optimized CAR T product incorporating enhancements in CAR design and T cell engineering to improve antitumor potency and T cell persistence. MB-101 includes a second-generation hinge optimized CAR containing mutations in the IgG4 linker to reduce off-target Fc interactions, the 4-1BB (CD137) co-stimulatory signaling domain for improved persistence of CAR T cells and the extracellular domain of CD19 as a selection/safety marker. To further improve persistence, central memory T cells are enriched and genetically engineered using a manufacturing process that limits *ex vivo* expansion to reduce T cell exhaustion and maintain a memory T cell phenotype.

#### **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 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 (“SEC”). Mustang was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit [mustangbio.com](https://mustangbio.com).

#### **About City of Hope**

City of Hope is an independent biomedical research and treatment center for cancer, diabetes and other life-threatening diseases. Founded in 1913, City of Hope is a leader

in [bone marrow transplantation](#) and immunotherapy such as [CAR T cell therapy](#). City of Hope's translational research and personalized treatment protocols advance care throughout the world. Human synthetic insulin, monoclonal antibodies, and [numerous breakthrough cancer drugs](#) are based on technology developed at the institution. [Translational Genomics Research Institute \(TGen\)](#) became a part of City of Hope in 2016. [AccessHope](#)<sup>TM</sup>, a wholly owned subsidiary, was launched in 2019, dedicated to serving employers and their health care partners by providing access to City of Hope's exceptional cancer expertise. A National Cancer Institute-designated comprehensive cancer center and a founding member of the National Comprehensive Cancer Network, City of Hope is ranked among the nation's "Best Hospitals" in cancer by U.S. News & World Report. Its main campus is located near Los Angeles, with [additional locations](#) throughout Southern California and in Arizona. For more information about City of Hope, follow us on [Facebook](#), [Twitter](#), [YouTube](#) or [Instagram](#).

### **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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