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Mustang Bio Announces Oral Presentation of Initial Clinical Data for MB-101 (IL13Ra2-specific CAR T cells) by City of Hope Investigators at the American Society of Gene and Cell Therapy 19th Annual Meeting

Early clinical findings suggest IL13Ra2-targeted CAR T cells is safe and well-tolerated, and capable of eliciting potent antitumor responses against recurrent multifocal glioblastoma

NEW YORK, May 05, 2016 (GLOBE NEWSWIRE) -- Mustang Bio, Inc. (“Mustang”), a Fortress Biotech (NASDAQ:FBIO) Company, today announced that an oral presentation related to its MB-101 (IL13Rα2-specific CAR T cells) product candidate in development was presented by City of Hope (“COH”) Investigators at the American Society of Gene and Cell Therapy 19th Annual Meeting (ASGCT) at the Marriott Wardman Park Hotel in Washington, DC.

Michael S. Weiss, Mustang Bio’s Executive Chairman, Interim Chief Executive Officer and President commented on the data, “We are very encouraged by the early safety and efficacy profile demonstrated by MB-101 (IL13Rα2-specific CAR T cells) to date. We were particularly impressed with the data presented today showing a patient treated at the first dose level who obtained an investigator designated complete response to MB-101. We believe this is the first demonstration of a response in a GBM patient utilizing CAR-T treatment. We are eager to continue the dose escalation to further assess the safety, activity and durability of MB-101 treatment at higher doses.” Mr. Weiss continued, “We would like to thank the investigators at City of Hope for all of their efforts on this important research program."

The following summarizes the oral presentation today:

Phase I Study of Second Generation Chimeric Antigen Receptor–Engineered T cells Targeting IL13Rα2 for the Treatment of Glioblastoma

The Phase I study abstract that was presented showed early data evaluating the safety, feasibility and bioactivity of weekly intracranial infusions of autologous IL13Rα2-specific CAR T cells in patients with recurrent IL13Rα2+ GBM. On this study, patients are treated on a 4-week therapeutic regimen consisting of 3 weekly intracranial infusions of IL13Rα2-specific CAR T cells followed by one rest week for toxicity and disease assessment. To date, treatment of the first low dose cohort of patients has been completed demonstrating that local delivery of IL13Rα2-specific CAR T cells post-surgical resection appeared to be safe and well-tolerated, with no grade 3 or higher toxicities attributed to the therapy reported. Importantly, early evidence for antitumor activity following CAR T cell administration was observed.

One patient of particular interest presented with a recurrent multifocal GBM, including one metastatic site in the spine and extensive leptomeningeal disease. This patient was initially treated per protocol with six local infusions of IL13Rα2-specific CAR T cells into the resection cavity of the largest recurrent tumor focus in the posterior temporal-occipital region. Encouragingly, this CAR T cell injection site remained stable without evidence of disease recurrence for over 7-weeks, while other disease foci distant from the CAR T cell injection site continued to progress. This patient was then treated on a compassionate use protocol with five weekly intraventricular infusions of IL13Rα2-specific CAR T cells without any other therapeutic interventions. The investigator reported today that following treatment the patient achieved a complete response. Early clinical findings suggest that intracranial delivery of second-generation IL13Rα2-targeted CAR T cells is safe and well-tolerated, and that after adoptive transfer, CAR T cells survive and maintain activity, capable of eliciting potent antitumor responses against recurrent multifocal glioblastoma.

About Glioblastoma multiforme (GBM)

Glioblastomas (GBM) are tumors that arise from astrocytes cells that make up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly and they are supported by a large network of blood vessels. GBM is the most common brain and central nervous system (CNS) malignancy, accounting for 15.1% of all primary brain tumors, and 55.1% of all gliomas. There are an estimated 12,120 new glioblastoma cases predicted in 2016 in the U.S. Malignant brain tumors are the most common cause of cancer-related deaths in adolescents and young adults aged 15-39 and the most common cancer occurring among 15-19 year olds in the U.S. (Brain Tumor Statistics. American Brain Tumor Association. December 2015). While GBM is a rare disease (2-3 cases per 100,000 person life years in the U.S. and E.U.), it is quite lethal with 5-year survival rates historically less than 10%. Chemotherapy with temozolomide and radiation are shown to extend mean survival from ~12 to ~15 months, while surgery remains the standard of care. GBM remains difficult to treat due to the inherent resistance of the tumor to conventional therapies. Treatment is further complicated by the susceptibility of the brain to damage, difficulty of the brain to repair itself and limitation to drugs crossing the blood brain barrier. Immunotherapy approaches targeting brain tumors offer promise over conventional treatments.

About MB-101 (IL13Rα2-specific CAR-T cells)

IL13Rα2 is an attractive target for CAR-T therapy as it has limited expression in normal tissue but is over-expressed on the surface of the majority of GBM. CAR T cells designed to express a membrane-tethered IL-13 receptor ligand (IL-13) incorporating a single point mutation that provides high affinity for IL13Rα2 and reduces binding to IL13Rα1 in order to

reduce healthy tissue targeting.

We are developing an optimized CAR-T product incorporating enhancements in CAR design and T cell engineering to improve antitumor potency and T cell persistence. We include a second generation hinge optimized CAR containing mutations in the IgG4 linker to reduce off-target Fc interactions, as well as the 41BB (CD137) co-stimulatory signaling domain for improved persistence of CAR T cells, and extracellular domain of CD19 as a selection/safety marker. In order to further improve persistence, central memory T cells are enriched and genetically engineered using a manufacturing process that limits ex vivo expansion in order to reduce T cell exhaustion and maintain a memory T cell phenotype.

About Mustang Bio
Mustang Bio, Inc., a Fortress Biotech Company, is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel cancer immunotherapy products designed to utilize the power of the patient's own immune system to eliminate cancer cells. Mustang aims to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest in the technologies, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently Mustang is developing proprietary Chimeric Antigen Receptor (CAR) engineered T cells (CAR-T) technology, which was licensed from Drs. Stephen Forman and Christine Brown's laboratory at the City of Hope National Medical Center (COH). CAR-T uses the patient's own T cells to engage and destroy specific tumors. The process involves selecting specific T cell subtypes, genetically engineering them to express chimeric antigen T cell receptors and placing them back in the patient where they recognize and destroy cancer cells. Mustang, through a research agreement with COH, will develop CARs across multiple cancers, including for AML and Brain Cancer. Both of the lead programs are in Phase I clinical trials. For more information, visit www.mustangbio.com.

Mustang Bio is a majority-owned subsidiary of Fortress Biotech.

About Fortress Biotech
Fortress Biotech, Inc. ("Fortress" or "the Company") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress plans to develop and commercialize products both within Fortress and through subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, the Company will leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies achieve their goals. Additionally, the Company will provide funding and management services to each of the Fortress Companies and, from time to time, the Company and the Fortress Companies will seek licensing, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit www.fortressbiotech.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. 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 price. Factors that could cause actual results to differ materially from those currently anticipated are: risks related to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; our ability to identify, acquire, close and integrate product candidates successfully and on a timely basis; risks relating to the results of research and development activities; 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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