



Fortress Biotech Announces Publication on MB-101 (IL13R α 2-specific CAR T cells) for the Treatment of Glioblastoma in *New England Journal of Medicine*

MB-101 is lead development candidate of Mustang Bio, a Fortress Company

Case study demonstrates MB-101 achieved complete remission in patient with recurrent glioblastoma

Phase 1 study of MB-101 in recurrent and refractory glioblastoma enrolling at City of Hope

New York, NY – December 28, 2016 – Fortress Biotech, Inc. (NASDAQ: FBIO) (“Fortress”), a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products, today announced that a patient case study from the Phase 1 clinical trial of MB-101 (IL13R α 2-specific, Chimeric Antigen Receptor engineered CAR T cells [CAR T cells]) for the treatment of glioblastoma (GBM) will be published in the December 29 edition of the *New England Journal of Medicine*. MB-101 is the lead development candidate of Mustang Bio, Inc., a Fortress Company.

The research, led by Stephen J. Forman, M.D., Christine Brown, Ph.D., and chief of neurosurgery Behnam Badie, M.D. at City of Hope, describes a 50-year-old male patient with recurrent multifocal glioblastoma and spinal tumors who had failed standard-of-care tumor resection, radiation therapy and temozolomide. The patient received multiple infusions of MB-101, which was developed from his own genetically modified T cells, first into the resected tumor cavity as part of the Phase 1 study, and then, following tumor growth distal to the resected cavity, under a compassionate use protocol the patient received MB-101 infusions into the ventricular system. This extremely novel approach had not been previously tested.

After treatment with intraventricular MB-101, regression of all intracranial and spinal tumors was observed, along with corresponding increases in levels of cytokines and immune cells in the cerebrospinal fluid. During intraventricular treatment, systemic dexamethasone was gradually eliminated, and the patient returned to normal life and work activities. The clinical response continued for 7.5 months after the initiation of MB-101. Infusions of MB-101 were well tolerated and not associated with any toxic effects of grade three or higher.

Dr. Lindsay A. Rosenwald, Fortress Biotech’s Chairman, President and Chief Executive Officer, said, “We are excited to share this unprecedented research conducted by Mustang’s partners at City of Hope, which confirms the potential of MB-101 to be a breakthrough immunotherapeutic targeted against GBM, an almost universally fatal brain tumor. MB-101’s compelling clinical activity adds to the growing pipeline of therapies developed by our Fortress Companies that have the potential to transform the treatment of life-threatening diseases.”

Michael S. Weiss, Mustang Bio’s Executive Chairman, commented, “We are extremely encouraged by the response seen in this patient. As the first patient ever to receive intraventricular delivery of CAR T cells for brain tumors, we see this as proof of concept that CAR T cells can be delivered safely and with remarkable effect to patients with GBM. This robust response has prompted the expansion of our Phase 1 study to evaluate intraventricular administration in a larger cohort of patients. Given the poor outcomes for patients with GBM, we believe if we see additional patients with this type of response that we can explore a possible accelerated approval pathway, similar to that proposed by some of the other CAR T companies, which are targeting different forms of cancer.”

Dr. Brown, Heritage Provider Network Professor in Immunotherapy, associate director of the T Cell Therapeutics Research Laboratory at City of Hope, and lead author on the case study, said, “This clinical experience provides remarkable evidence of the potential of CAR T cell immunotherapy to improve the treatment of patients with aggressive brain tumors, while preserving neurological function and minimizing toxic side effects seen with other therapies. We are very encouraged by the regression of all brain and spinal lesions, a response that has been unparalleled to date and may warrant future studies of MB-101 in a wide variety of patients. We look forward to continuing our work with Mustang on this promising therapy.”

City of Hope is evaluating MB-101 in an ongoing Phase 1 study in patients with recurrent and refractory malignant GBM. For additional information, visit [ClinicalTrials.gov: NCT02208362](https://clinicaltrials.gov/ct2/show/study/NCT02208362).

About Glioblastoma multiforme (GBM)

Glioblastomas (GBM) are tumors that arise from astrocyte 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 percent of all primary brain tumors, and 55.1 percent of all gliomas (Brain Tumor Statistics. American Brain Tumor Association. December 2015). There were roughly 27,000 new glioblastoma cases worldwide in 2015 (Global Data. December 2016).

While GBM is a rare disease (2-3 cases per 100,000 person life years in the U.S. and EU), it is quite lethal with five-year survival rates historically less than 10 percent. Chemotherapy with temozolomide and radiation are shown to extend median survival from approximately 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, the difficulty of the brain in repairing itself and the limitations of drugs in crossing the blood-brain barrier. Immunotherapy approaches targeting brain tumors offer promise over conventional treatments.

About MB-101 (IL13R α 2-specific CAR T cells)

IL13R α 2 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 cells. 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 α 2 and reduces binding to IL13R α 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 41BB (CD137) co-stimulatory signaling domain for improved persistence of CAR T cells and 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., 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 out-licensing or bringing the technologies to market. Mustang is currently 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, by 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, plans to develop CARs across multiple cancers. Its lead programs in acute myeloid leukemia and brain cancer are in Phase 1 clinical trials.

Mustang is registered under the Securities Exchange Act of 1934, as amended, and files periodic reports with the U.S. Securities and Exchange Commission. For more information, visit www.mustangbio.com.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. Additionally, Fortress recently acquired a controlling interest in National Holdings Corporation (NASDAQ: NHLD), a diversified independent brokerage company (together with its subsidiaries, “NHLD”). In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may seek licensings, 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 include: the risk that additional responders like the one described here will not be seen in the future; even if we do see more responders, we still may not be eligible for or may not receive accelerated approval; risks related to our growth strategy; risks relating to the results of research and development activities; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; 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 may be required by law.

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