November 7, 2024

Mustang Bio Granted Orphan Drug Designation by U.S. FDA for MB-108 (HSV-1 oncolytic virus) to Treat Malignant Glioma

MB-108 (HSV-1 oncolytic virus) is active and well tolerated in patients with recurrent glioblastoma in ongoing Phase 1 clinical trial

Preclinical data support a novel combination of MB-108 (HSV-1 oncolytic virus) and MB-101 (IL13Rα2-targeted CAR-T cell therapy) to optimize clinical results

WORCESTER, Mass., Nov. 07, 2024 (GLOBE NEWSWIRE) -- Mustang Bio, Inc. ("Mustang" or the "Company") (Nasdaq: MBIO), a clinical-stage biopharmaceutical company focused on translating today's medical breakthroughs in cell therapies into potential cures for difficult-to-treat cancers, today announced that the U.S. Food and Drug Administration ("FDA") has granted Orphan Drug Designation to Mustang for MB-108, a herpes simplex virus type 1 ("HSV-1") oncolytic virus, for the treatment of malignant glioma.

The FDA grants Orphan Drug Designation to drugs and biologics that are intended for safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S. Orphan Drug Designation provides certain incentives, such as tax credits toward the cost of clinical trials upon approval and prescription drug user fee waivers. If a product receives Orphan Drug Status from the FDA, that product is entitled to seven years of market exclusivity for the disease in which it has Orphan Drug designation, which is independent from intellectual property protection.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, said, "The Orphan Drug Designation for MB-108 is significant for Mustang, as it could provide additional market exclusivity and we hope to advance MB-108, in combination with MB-101, as a potential treatment option for patients living with malignant glioma, including patients with recurrent glioblastoma ("GBM") and high-grade astrocytomas, where there is historically a median overall survival of six months. Our novel therapeutic strategy, combining our MB-108 oncolytic virus with MB-101 CAR-T cell therapy, could be the first-ever industry-sponsored trial of its kind for the treatment of malignant glioma. As such, Mustang plans to also request Orphan Drug Designation from the FDA for MB-101 (IL13Rα2-targeted CAR-T cell therapy) in malignant gliomas. These advancements highlight our dedication to potentially improving outcomes for patients battling difficult-to-treat cancers."

As previously reported, preclinical data presented at the American Association for Cancer Research ("AACR") Annual Meeting in 2022 supported a combination therapy to potentially optimize results to treat recurrent GBM. The combination leverages MB-108 to reshape the tumor microenvironment ("TME") and make cold tumors "hot," thereby potentially improving the efficacy of MB-101 CAR-T cell therapy. Data presented separately on MB-101 and MB-108 showed that administration of these therapies was well tolerated in recurrent GBM patients. Two patients treated solely with MB-101 who had high levels of intratumoral CD3+ T cells pre-therapy (i.e., "hot" tumors) achieved complete responses lasting 7.5 and 31+ months, respectively. Importantly, of the 53 City of Hope Phase 1 patients disclosed at AACR in 2022, these 2 complete responses were observed in the 2 patients with the "hottest" tumors prior to treatment with MB-101. Phase 1 clinical trials of MB-101 at City of Hope and of MB-108 at The University of Alabama at Birmingham continue to enroll patients.

The Company's ability to further develop the MB-109 program for recurrent GBM and high-grade astrocytomas is contingent upon raising additional funding and / or consummating a strategic partnership.

About MB-109 (MB-101 (IL13Rα2 targeted CAR-T cells) + MB-108 oncolytic virus)
MB-109 is Mustang's designation for the treatment regimen combining MB-101 (IL13Rα2-targeted CAR-T cell therapy licensed from City of Hope) with MB-108 (HSV-1 oncolytic virus licensed from Nationwide Children's Hospital). The combination is designed to leverage MB-108 to make cold tumors "hot" and potentially improve the efficacy of MB-101 CAR-T cell therapy. MB-108 oncolytic virus is first injected to infect tumor cells which, in turn, leads to reshaping of the TME through recruitment of endogenous CD8- and CD3-positive effector T-cells. This inflamed TME potentially permits MB-101 CAR-T cells injected into and around the tumor to better infiltrate into and throughout the tumor mass, undergo activation and, ideally, effect tumor cell killing.

About Mustang Bio
Mustang Bio, Inc. is a clinical-stage biopharmaceutical company focused on translating today's medical breakthroughs in cell therapies into potential cures for difficult-to-treat cancers. 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. Mustang's common stock is registered under the Securities Exchange Act of 1934, as amended, and Mustang 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 www.mustangbio.com.

Forward-Looking Statements
This press release contains "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, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. The Company's forward-looking statements, include, but are not limited to, any statements relating to our growth strategy and product development programs, including the timing of and our ability to make regulatory filings such as INDs and other applications and to obtain

regulatory approvals for our product candidates, statements concerning the potential of therapies and product candidates and any other statements that are not historical facts. Actual events or results may differ materially from those described in this press release due to a number of risks and uncertainties. Risks and uncertainties include, among other things, our need for substantial additional funds in the immediate future, risks that any actual or potential clinical trials described herein may not initiate or complete in sufficient timeframes to advance the Company's corporate objectives, or at all, or that promising early results obtained therefrom may not be replicable, risks related to the satisfaction of the conditions necessary to transfer the lease of the Company's manufacturing facility to a potential transferee and receive the contingent payment in connection with the sale of such facility in the anticipated timeframe or at all; whether the purchaser of the Company's manufacturing facility is able to successfully perform its obligation to produce the Company's products under the manufacturing services agreement on a timely basis and to acceptable standards; disruption from the sale of the Company's manufacturing facility making it more difficult to maintain business and operational relationships; negative effects of the announcement or the consummation of the transaction on the market price of the Company's common stock; significant transaction costs; the development stage of the Company's primary product candidates, 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; government regulation; patent and intellectual property matters; competition; as well as other risks described in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K filed on March 11, 2024, subsequent Reports on Form 10-Q, and our other filings we make with the SEC. 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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