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Mustang Bio and Nationwide Children's Hospital Receive Orphan Drug Designation for MB-108 (Oncolytic Virus C134) for the Treatment of Malignant Glioma

NEW YORK and COLUMBUS, Ohio, May 16, 2019 (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 Nationwide Children's Hospital ("Nationwide Children's"), one of America's largest not-for-profit freestanding pediatric health care systems providing wellness, preventive, diagnostic, treatment and rehabilitative care for infants, children and adolescents, as well as adult patients with congenital disease, announced today that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to MB-108 (oncolytic virus C134) for the treatment of malignant glioma, a type of brain cancer with a median survival of less than 18 months. Nationwide Children's has exclusively licensed oncolytic virus C134 to Mustang.



Martina Sersch, M.D., Ph.D., Chief Medical Officer of Mustang, said, "We are very pleased to receive Orphan Drug Designation for MB-108, as it provides Mustang with additional market exclusivity and financial incentives to advance the oncolytic virus. MB-108 has demonstrated the potential to address an area of high unmet medical need, and we believe it is an important new treatment for patients with malignant glioma. Mustang intends to combine MB-108 with MB-101 (IL13R α 2-specific CAR) to potentially enhance efficacy in treating glioblastoma multiforme."

A Phase 1 clinical trial evaluating MB-108 in recurrent glioblastoma multiforme is being conducted at the University of Alabama at Birmingham (“UAB”) and is led by James Markert, M.D., Chairman of the Department of Neurosurgery at UAB, who developed MB-108 (C134) in collaboration with Kevin Cassady, M.D., principal investigator in the Center for Childhood Cancer and Blood Diseases at The Research Institute at Nationwide Children’s. MB-108 (C134) is a second-generation attenuated herpes simplex virus type 1 (HSV-1) oncolytic virus that has improved replication in tumors in murine models, but with the same toxicity profile as its first-generation predecessors. In these preclinical studies, it not only demonstrates direct anti-tumor activity, but also elicits an immune response that can reverse tumor-associated immunosuppression.

“MB-108 has demonstrated promise in preclinical studies, and we are delighted that it has received Orphan Drug Designation in acknowledgement of its potential to help those living with malignant glioma,” said Dr. Cassady, also a physician in Infectious Diseases at Nationwide Children’s. “We will continue to learn more about MB-108 in our Phase 1 clinical trial and are excited about developing it in collaboration with UAB and Mustang.”

The FDA grants Orphan Drug Designation to drugs and biologics that are intended for the 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 and prescription drug user fee waivers. If a product holding Orphan Drug Designation receives the first FDA approval for the disease in which it has such designation, the product is entitled to seven years of market exclusivity, which is independent from intellectual property protection.

About Mustang Bio

Mustang Bio, Inc. (“Mustang”) 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 and CRISPR/Cas9-enhanced CAR T therapies across multiple cancers, as well as a lentiviral gene therapy for XSCID. 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.

About Nationwide Children’s Hospital

Named to the Top 10 Honor Roll on *U.S. News & World Report’s* 2018-19 list of “Best Children’s Hospitals,” Nationwide Children’s Hospital is one of America’s largest not-for-profit freestanding pediatric health care systems providing wellness, preventive, diagnostic, treatment and rehabilitative care for infants, children and adolescents, as well as adult patients with congenital disease. Nationwide Children’s has a staff of more than 13,000 providing state-of-the-art pediatric care during more than 1.4 million patient visits annually. As home to the Department of Pediatrics of The Ohio State University College of Medicine, Nationwide Children’s physicians train the next generation of pediatricians and pediatric specialists. The Research Institute at Nationwide Children’s Hospital is one of the Top 10 National Institutes of Health-funded freestanding pediatric research facilities. More

information is available at NationwideChildrens.org.

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.

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