

# Mustang Bio Announces Strategic Manufacturing Partnership and Portfolio Updates

uBriGene (Boston) Biosciences to acquire Mustang Bio's Worcester manufacturing facility for total consideration of up to \$11 million and enters into strategic manufacturing partnership to support MB-106 and future pipeline

Company optimizes resources to focus on advancing lead CD20 CAR T program, GBM program, and in vivo CAR T platform technology from Mayo Clinic

Transaction and partnership with uBriGene, portfolio optimization, restructuring and recent loan repayment expected to significantly reduce annualized operating and interest expense by at least \$28 million and ensure focus on data readouts for key programs

WORCESTER, Mass., May 18, 2023 (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 and gene therapies into potential cures for difficult-to-treat cancers and rare genetic diseases, today announced a strategic update, including anticipated milestones for 2023. Mustang intends to optimize the allocation of its resources and focus on MB-106, MB-109, and *in vivo* CAR T platform technology. Additionally, Mustang announced a partnership with uBriGene (Boston) Biosciences Inc. ("uBriGene"), the U.S. subsidiary of uBriGene Group, a leading cell and gene therapy contract development and manufacturing organization ("CDMO"), which includes the sale of the Company's development, manufacturing and analytical testing facility in Worcester, Massachusetts to uBriGene.

Under the terms of an asset purchase agreement between Mustang and uBriGene, uBriGene will acquire Mustang's state-of-the-art clinical- and commercial-scale cell and gene therapy manufacturing facility in Worcester, Massachusetts, for a total consideration of \$11 million. This consideration includes \$6 million payable upfront plus an additional \$5 million payable upon Mustang raising \$10 million in gross proceeds from equity raises following the closing of the transaction. The closing of the transaction is subject to the satisfaction of certain conditions, including approval of transfer of the Company's lease to uBriGene by the owner of the building (an affiliate of the University of Massachusetts Chan Medical School) and the acceptance of offers of employment with uBriGene or its affiliates by certain key current Mustang employees. Subject to satisfaction of conditions, the Company expects the transactions to close in June 2023.

Subject to closing, the parties will enter into a manufacturing supply agreement, under which uBriGene will manufacture Mustang's lead product candidates, including continuing to support MB-106 manufacturing for the ongoing multi-center Phase 1/2 trial.

Mustang's Worcester facility is a 27,000 square foot, cutting edge cGMP facility supporting process development, manufacturing and analytical testing, designed with the flexibility to expand and support various cell and gene therapy production requirements and capacities. uBriGene intends to expand the Worcester site's capabilities while leveraging Mustang's experienced staff and robust quality and operating systems to manufacture a broader portfolio of advanced modalities. uBriGene will also offer their expertise in preclinical research services and late-stage and commercial manufacturing of advanced therapy products with respect to product and process characterization, and regulatory inspections.

Manuel Litchman, M.D., President and Chief Executive Officer of Mustang, commented, "We are very pleased to have found a great partner for the manufacturing of our CAR T cell and gene therapies, and we believe that this strategic partnership with uBriGene will meet our portfolio manufacturing needs to reach critical upcoming data inflection points, while extending our cash runway. I want to thank our manufacturing team for their dedication in building and growing our Worcester facility since it opened in 2018. While we are optimizing our resources at Mustang, we look forward to continuing to work with many of our colleagues in this new capacity, as our CDMO."

"This acquisition is important to uBriGene's commitment to support the development, clinical, and commercial supply of cell and gene therapies to sustain industry demand and provide new CDMO options," said Alex Chen, President of uBriGene. "We look forward to working together with the University of Massachusetts Chan Medical School and local biotechnology companies to continue to advance the manufacturing ecosystem in the Greater Boston region. This partnership enables us to expand rapidly to create a North American presence and offer the same high-quality cell and gene therapy development and manufacturing capabilities for the U.S. that we currently provide in Asia, including to support Mustang Bio's lead clinical-stage CAR-T program."

## **Mustang Bio Strategic Portfolio Updates**

#### CAR T Cell Therapies

After a review of its portfolio of product candidates to determine the future strategy of its programs and the proper allocation of its resources, Mustang will discontinue development of its MB-102, its CD123-targeted CAR T cell therapy, as well as its HER2-, CS1- and PSCA-targeted CAR T cell therapy programs, comprising a portion of the Company's portfolio of CAR T cell therapies being developed by the Company in partnership with City of Hope.

Mustang will continue to work with Fred Hutchinson Cancer Center ("Fred Hutch") to develop MB-106 (CD20-targeted CAR T cell therapy) and with Mayo Clinic to develop its *in vivo* CAR T platform technology. Mustang will also continue to work with City of Hope and with Nationwide Children's Hospital on the development of MB-109 (MB-101 CAR T cell therapy targeting IL13Rα2 on malignant glioma cells + MB-108 oncolytic virus to potentially make these tumors more susceptible to killing by the CAR-T cells).

### Gene Therapies

Additionally, based on a review of the data from the investigator-sponsored clinical trials of

the gene therapy for X-linked severe combined immunodeficiency ("XSCID") that has been licensed to Mustang Bio, enrollment to these trials has been paused. We await data from new investigator-sponsored trials being planned by our partners that will test a modified version of the current lentiviral vector prior to initiating multicenter Mustang-sponsored trials in both the newborn and previously transplanted patient populations. No safety concerns in the trials utilizing the current vector have been noted to date and no insertional mutagenesis or malignancy has been detected in either of the two investigator-sponsored trials. However, Mustang has made the decision to delay initiating its own sponsored trials out of an abundance of caution, and once we have had the opportunity to review the emerging data from the planned trials utilizing the modified vector, Mustang expects to provide more information on timelines. The delayed start of Mustang's multicenter trials for XSCID will allow the Company to utilize the safest known vector available in its clinical trials and reduce Mustang's near-term operating expense.

In addition, in 2023 we look forward to treating a second RAG1-SCID patient with our MB-110 LV-RAG1 *ex vivo* lentiviral gene therapy in the ongoing investigator-sponsored Phase 1/2 multicenter clinical trial taking place in Europe. Furthermore, we hope to provide an update regarding the research collaboration with Frank J. Staal, Ph.D., from Leiden University to develop additional lentiviral gene therapies.

"Upon completion of a thorough, strategic review of our portfolio of CAR T and gene therapies, it was determined that Mustang's resources should be focused and allocated to benefit our lead clinical-stage CAR T programs, which could provide potential curative treatment options for certain hematologic cancers and solid tumors, supported by data-todate. As previously reported, MB-106 continues to demonstrate high efficacy and a favorable safety profile in a Phase 1 investigator-sponsored trial at Fred Hutch, with an overall response rate of 96% and complete response rate of 75% in a wide range of hematologic malignancies, including Waldenstrom macroglobulinemia ("WM"). Given this, Mustang plans to treat patients with WM in the Phase 1 portion of its multicenter MB-106 clinical trial to support a fast-to-market Phase 2 strategy for this indication, with the first pivotal Phase 2 WM patient potentially to be treated in the first guarter of 2024. Data from the Fred Hutch clinical trial also support the potential of MB-106 to be administered as outpatient therapy and provide a best-in-class immunotherapy option for patients treated previously with CD19directed CAR T cell therapy. We look forward to data from the Fred Hutch clinical trial to be presented at medical meetings in the second guarter of 2023, and initial data from Mustang's multicenter clinical trial to be disclosed shortly as well. 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 with recurrent GBM. Additionally, Mustang is excited about advancing the preclinical investigation of these two programs as the combination therapy MB-109 and plans to file an IND for this therapy this year. Concentrating our priorities and postponing the initiation of the MB-107 and MB-207 pivotal trials, along with maintaining a reduced headcount, reduces Mustang's burn and extends our cash runway. This allows Mustang to allocate more resources to advance our lead clinical-stage programs and potentially expedite the achievement of several near-term milestones across our portfolio of product candidates for difficult-to-treat cancers," said Dr. Litchman.

#### General Corporate

Mustang expects to incur severance charges related to the facility transaction of approximately \$2.1 million, which Mustang expects will be offset by future annualized

operating savings of at least \$24 million including savings related to personnel, facility and clinical operations and optimization of the development portfolio. The Company also reduced annual interest expense by approximately \$4.3 million in April 2023 after repaying and terminating its Loan and Security Agreement with Runway Growth Finance Corp.

## About uBriGene (Boston) Biosciences Inc.

uBriGene (Boston) Biosciences Inc. is dedicated to providing one-stop viral vector-based CDMO services for research and clinical applications. It has established integrated innovative biologics CDMO platforms that provide GMP-level plasmid preparation, viral packaging, and T-cell production services for large-scale CAR-T productions. In addition, the company also provides viral vectors, including adenoviral and lentiviral vectors to meet the demands of research and/or manufacturing applications. With its fermentation capacity ranging from 5L to 500L, uBriGene offers a versatile selection of research-grade, GMP-ready, or GMP-grade plasmids for research and clinical applications respectively. uBriGene currently operates two state-of-the-art GMP facilities, including 21 clean suites with a total area of over 133,000 sq ft. For more information, visit <a href="https://www.ubrigene.com">www.ubrigene.com</a>.

#### **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 lentiviral gene therapies for severe combined immunodeficiency. 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 <a href="https://www.mustangbio.com">www.mustangbio.com</a>.

#### **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, among others, statements about the Company's expectations with respect to the consummation of the sale of its manufacturing facility and its ability to fund its operations, including continued investment in its research and development pipeline; the Company's anticipated savings and expenses relating to the consummation of the sale of its manufacturing facility, the discontinuance of its MB-102, its CD123-targeted CAR T cell therapy, as well as its HER2-, CS1- and PSCA-targeted CAR T cell therapy programs, the postponing of the MB-107 and MB-207 pivotal trials and the related reduction in the Company's workforce; and the Company's plans and timeline regarding its XSCID program. 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, risks related to the satisfaction of the conditions to closing the transaction—including the conditions specifically described in this press release —in the anticipated timeframe or at all; whether uBriGene 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; whether the Company is able to raise \$10 million in gross proceeds from equity raises following the closing of the transaction and receive the contingent portion of the consideration for the sale of the manufacturing facility to uBriGene; whether the Company's expenses are as predicted; disruption from the transaction 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 and the related risks involved in drug development, clinical trials and the uncertainties around regulatory reviews and approvals; other business effects, including the effects of industry, market, economic, political or regulatory conditions; as well as other risks described in Part I, Item 1A, "Risk Factors," in our Annual Report on Form 10-K filed on March 30, 2023, 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.

## **Company Contact:**

Jaclyn Jaffe Mustang Bio, Inc. (781) 652-4500 ir@mustangbio.com

#### **Investor Relations Contact:**

Daniel Ferry LifeSci Advisors, LLC (617) 430-7576 daniel@lifesciadvisors.com

## **Media Relations Contact:**

Tony Plohoros 6 Degrees (908) 591-2839 tplohoros@6degreespr.com



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