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Mustang Bio and Minaris Regenerative Medicine Sign Technology Transfer and GMP Manufacturing Agreement for MB-107 Lentiviral Gene Therapy for X-Linked Severe Combined Immunodeficiency

WORCESTER, Mass. and MUNICH, Germany, Nov. 23, 2020 (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 Minaris Regenerative Medicine GmbH ("Minaris"), a leading contract development and manufacturing service provider for the cell and gene therapy industry, today announced that they have signed an agreement to enable technology transfer and GMP clinical manufacturing of Mustang's MB-107 lentiviral gene therapy program for the treatment of X-linked severe combined immunodeficiency ("XSCID"), also known as bubble boy disease, in Europe.

Under the terms of the agreement, Minaris will perform technology transfer of the manufacturing and analytical processes, as well as their adoption to the European regulatory environment, for the GMP-compliant manufacturing of the drug product at its site in Ottobrunn, Germany, with the goal of supplying clinical trials in Europe.

"We look forward to a productive and successful partnership with Mustang where Minaris will be able to support them with our extensive experience in the clinical and commercial manufacturing of autologous gene therapies," said Dusan Kosijer, Managing Director of Minaris. "We are eager to work together with Mustang in the fight against this devastating disease."

"This agreement with Minaris is an important step in supporting expansion of our MB-107 pivotal clinical trial into Europe," said Manuel Litchman, M.D., President and Chief Executive Officer of Mustang. "We look forward to working with Minaris to grow our geographic footprint and bring this potential life-saving therapy to XSCID patients in need internationally."

MB-107 is currently being assessed in a Phase 1/2 clinical trial for XSCID in newly diagnosed infants under the age of two at St. Jude Children's Research Hospital, UCSF

Benioff Children's Hospital in San Francisco and Seattle Children's Hospital. Mustang submitted an investigational new drug application ("IND") to the FDA to initiate a pivotal multi-center Phase 2 clinical trial of MB-107 in this same patient population. The trial is expected to enroll 10 patients who, together with 15 patients enrolled in the current multi-center trial led by St. Jude, will be compared with 25 matched historical control patients who have undergone hematopoietic stem cell transplantation. The primary efficacy endpoint will be event-free survival. The initiation of this trial is expected soon. Mustang is targeting topline data from this trial in the second half of 2022.

The FDA granted Rare Pediatric Disease, Orphan Drug and Regenerative Medicine Advanced Therapy Designations to MB-107 for the treatment of XSCID in newly diagnosed infants.

About X-linked Severe Combined Immunodeficiency ("XSCID")
X-linked severe combined immunodeficiency is a rare genetic disorder that occurs in approximately 1 per 225,000 births. It is characterized by the absence or lack of function of key immune cells, resulting in a severely compromised immune system and death by one year of age if untreated. Patients with XSCID have no T-cells or natural killer cells. Although their B-cells are normal in number, they are not functional. As a result, XSCID patients are usually affected by severe bacterial, viral or fungal infections early in life and often present with interstitial lung disease, chronic diarrhea and failure to thrive.

The specific genetic disorder that causes XSCID is a mutation in the gene coding for the common gamma chain ("γc"), a protein that is shared by the receptors for at least six interleukins. These interleukins and their receptors are critical for the development and differentiation of immune cells. The gene coding for γc is known as IL-2 receptor gamma, or IL2RG. Because IL2RG is located on the X-chromosome, XSCID is inherited in an X-linked recessive pattern, resulting in almost all patients being male.

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 chimeric antigen receptor T cell (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 ("SEC"). Mustang was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.mustangbio.com.

About Minaris Regenerative Medicine
Minaris Regenerative Medicine is a global contract development and manufacturing organization (CDMO) for cell and gene therapies. We offer our clients high value clinical and commercial manufacturing services, development solutions, and technologies. We are pioneers in the field with more than 20 years' experience providing outstanding quality and reliability. Our facilities in the US, Europe, and Asia allow us to supply patients worldwide with life-changing therapies. Minaris Regenerative Medicine is wholly owned by Showa Denko Materials Co., Ltd. For more information, please visit www.rm.minaris.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, 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, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

Minaris Regenerative Medicine Contact:

Luc St-Onge, Ph.D.
Global Head of Sales and Marketing
Minaris Regenerative Medicine GmbH

E-Mail: press@rm.minaris.de
Phone: +49 (0)89 700 9608-0

Mustang Bio Contacts:

Jaclyn Jaffe and William Begien
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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