Morphogenesis, Inc. and CohBar, Inc. Announce Positive Results from Phase 1b Trial of IFx-Hu2.0, a Novel Personalized Cancer Vaccine, in Checkpoint Inhibitor Resistant Advanced Merkel Cell Carcinoma (MCC) and Cutaneous Squamous Cell Carcinoma (cSCC)

IFx-Hu2.0 demonstrated to have a promising safety profile at all 3 dose schedules tested

5 of 7 (71%) of patients achieved durable systemic anti-tumor responses following IFx-Hu2.0 therapy and rechallenge with an immune checkpoint inhibitor (ICI) in patients who exhibited primary resistance to ICIs

Translational biomarker data underscores IFx-Hu2.0 mechanism; Demonstrates activation of systemic tumor-specific immune responses

Data presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

TAMPA, Fla. and MENLO PARK, Calif., June 05, 2023 (GLOBE NEWSWIRE) -- Morphogenesis, Inc. (“Morphogenesis”), a privately-held Phase 2/3 clinical-stage biotechnology company developing novel personalized cancer vaccines and tumor microenvironment modulators to overcome primary and acquired resistance to current immunotherapies, and CohBar, Inc. (NASDAQ: CWBR) (“CohBar”), today announced positive initial results from an exploratory analysis of anti-tumor responses to rechallenge with an ICI following protocol directed IFx-Hu2.0 therapy among patients with advanced MCC or cSCC who exhibited primary resistance to ICIs.

The abstract titled, “Phase 1b trial of IFx-Hu2.0, a novel personalized cancer vaccine, in checkpoint inhibitor resistant Merkel cell carcinoma and cutaneous squamous cell carcinoma,” was presented by Andrew Brohl, MD, H. Lee Moffitt Cancer Center and Research Institute in a poster presentation as part of the Melanoma/Skin Cancers – Advanced/Metastatic Diseases session held at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place June 2-6, 2023 in Chicago, IL.

“While patients with advanced Merkel cell carcinoma and cutaneous Squamous cell carcinoma exhibit high response rates to immune checkpoint inhibitor therapy, the approximately 50% of patients who fail to respond have limited treatment options. We are particularly encouraged by the results in patients with advanced Merkel cell who exhibited
primary resistance to ICIs, where 4 of 5 (80%) achieved long lasting, major objective anti-tumor responses on rechallenge with an ICI within the same checkpoint axis,” noted Dr. James Bianco, Chief Executive Officer of Morphogenesis. “The potential for IFx-Hu2.0 adjunctive therapy to pembrolizumab in the first line treatment of advanced MCC could overcome primary resistance, allowing higher response rates than pembrolizumab alone.”

IFx-Hu2.0 is Morphogenesis’ lead personalized cancer vaccine candidate that is designed to overcome primary resistance to checkpoint inhibitors. In a Phase 1 study in advanced melanoma, biomarker analyses demonstrated robust immune priming effects of IFx administration. The ongoing Phase 1b study evaluates IFx-Hu2.0 in a two-stage study design to assess safety and to examine the effects of repeated weekly dosing up to 3 weeks on the magnitude of the ensuing systemic immune response to determine the optimal dose and schedule for the company’s planned Phase 2/3 registration directed trial.

As reported at ASCO, following completion of protocol directed therapy, 5 patients with advanced MCC and 2 patients with cSCC who, prior to study entry, failed anti-PD(L)1 therapy were re-treated with anti-PD(L)1 monotherapy: pembrolizumab (3) or avelumab (2) in MCC and cemiplimab (2) in cSCC. Four of 5 (80%) patients with advanced MCC and 1 of 2 (50%) patients with cSCC, or 5 of 7 total (71%), experienced objective anti-tumor responses to ICI rechallenge in this setting, with duration of response ongoing in 4 patients (7+, 8+, 9+, 20+ months) and one response lasting 23 months. All 4 patients with advanced MCC with post-protocol response to anti-PD(L1) therapy had previously experienced progression to this same drug class prior to treatment on protocol.

Based on the positive preliminary results seen to-date, an additional 11 patients are planned for enrollment in the expansion stage of the Phase 1b study using the weekly x 3 dosing schedule. Additional exploratory/biomarker analyses are planned.

For more information about the company’s ongoing Phase 1b IFx-Hu2.0 study, visit Clinicaltrials.gov and reference Identifier NCT04160065.

Morphogenesis and CohBar recently announced that they have entered into a definitive merger agreement for an all-stock transaction to form a company combining expertise and resources to advance a late-stage oncology pipeline. The combined company will focus on advancing Morphogenesis’ two technologies that seek to overcome the major obstacles that limit the effectiveness of current immunotherapies in treating cancer. The combined company is expected to operate under the name “TuHURA Biosciences, Inc.” and to trade on The Nasdaq Capital Market (“Nasdaq”). The transaction is expected to close in the third quarter of 2023.

About Immune Fx (IFx) Personalized Cancer Vaccines

IFx-Hu2.0 administration involves a simple injection into the patient’s tumor of a proprietary gene that encodes for an immunogenic bacterial protein which is expressed on the surface of the tumor cell. Recognizing the bacterial protein as being foreign, the patient’s immune system is activated “ingesting” the tumor cell and educating the immune system to all of the patient’s tumor’s neoantigens resulting in the production of tumor specific antibodies and cytotoxic T cells. The presence of activated T cells overcomes resistance to checkpoint inhibitors allowing checkpoint released activated T cells to seek out and destroy the tumor.
Additionally, Morphogenesis is advancing its CD22 targeted, mRNA vaccine (IFx-Hu3.0), toward IND-enabling studies in 2024 for intravenous or autologous whole cell administration for the treatment of B cell malignancies like diffuse large B-cell lymphoma (DLBCL).

About Morphogenesis, Inc.

Morphogenesis is a Phase 2/3 clinical-stage biotechnology company developing novel personalized cancer vaccines and tumor microenvironment modulators to overcome primary and acquired resistance to immunotherapies. The company’s lead personalized cancer vaccine candidate, IFx-Hu2.0, is designed to overcome primary resistance to checkpoint inhibitors. Morphogenesis is preparing to initiate a single randomized placebo-controlled Phase 2/3 registration trial of IFx-Hu2.0 administered as an adjunctive therapy to Keytruda® (pembrolizumab) in first line treatment for advanced Merkel Cell Carcinoma. In addition to its personalized cancer vaccines the company is also developing first in class bi-functional antibody drug conjugates (ADCs) designed to reprogram the tumor microenvironment by targeting a recently characterized Delta receptor on Myeloid Derived Suppressor Cells inhibiting their immunosuppressive capabilities while localizing checkpoint inhibitor(s) in the tumor microenvironment.

For additional information, please visit www.morphogenesis-inc.com.

About CohBar

CohBar (NASDAQ: CWBR) is a clinical-stage biotechnology company leveraging the power of the mitochondria and the peptides encoded in its genome to develop potential breakthrough therapeutics targeting chronic and age-related diseases with limited to no treatment options.

For additional company information, please visit www.cohbar.com and engage with us on LinkedIn.

No Offer or Solicitation

This communication is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any proxy, consent, authorization, vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of the U.S. Securities Act of 1933, as amended.

Additional Information About the Proposed Transaction for Investors and Stockholders

In connection with the proposed transaction between CohBar and Morphogenesis (the “Proposed Transaction”), CohBar intends to file relevant materials with the U.S. Securities and Exchange Commission (the “SEC”), including a registration statement on Form S-4 that will contain a proxy statement/prospectus of CohBar. This press release is not a substitute for the registration statement or for any other document that CohBar may file with the SEC in connection with the Proposed Transaction. COHBAR URGES INVESTORS AND
STOCKHOLDERS TO READ THE REGISTRATION STATEMENT, PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT MAY BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT COHBAR, MORPHOGENESIS, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and stockholders will be able to obtain free copies of the proxy statement/prospectus and other documents filed by CohBar with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders should note that CohBar communicates with investors and the public using its website (www.cohbar.com), including its investor relations website (https://cohbar.com/investors), where anyone will be able to obtain free copies of the proxy statement/prospectus and other documents filed by CohBar with the SEC, and stockholders are urged to read the proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the Proposed Transaction.

Participants in the Solicitation

CohBar, Morphogenesis and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from CohBar’s stockholders in connection with the Proposed Transaction. Information about CohBar’s directors and executive officers including a description of their interests in CohBar is included in CohBar’s most recent Annual Report on Form 10-K (as amended), including any information incorporated therein by reference, as filed with the SEC. Additional information regarding these persons and their interests in the transaction will be included in the proxy statement/prospectus relating to the Proposed Transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

Forward-Looking Statements

This news release contains forward-looking statements that are not historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and other future conditions. In some cases you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “should,” “would,” “project,” “plan,” “expect,” “goal,” “seek,” “future,” “likely” or the negative or plural of these words or similar expressions. Examples of such forward-looking statements include but are not limited to express or implied statements regarding CohBar’s or Morphogenesis’ management team’s expectations, hopes, beliefs, intentions or strategies regarding the future including, without limitation, statements regarding: the Proposed Transaction and the expected effects, perceived benefits or opportunities and related timing with respect thereto, expectations regarding clinical trials and research and development programs, in particular with respect to Morphogenesis’ IFx-Hu2.0 product candidate, its IFx-Hu3.0 preclinical program, and its TME modulators development program, and any developments or results in connection therewith; the anticipated timing of the results from those studies and trials; and the expected trading of the combined company’s stock on the Nasdaq Capital Market. In addition, any statements that refer to projections, forecasts or other characterizations of
future events or circumstances, including any underlying assumptions, are forward-looking statements. You are cautioned that such statements are not guarantees of future performance and that actual results or developments may differ materially from those set forth in these forward-looking statements. Factors that could cause actual results to differ materially from these forward-looking statements include: the risk that the conditions to the closing or consummation of the Proposed Transaction are not satisfied, including the failure to obtain stockholder approval for the Proposed Transaction; the risk that the previously announced concurrent financing in connection with the Proposed Transaction is not completed in a timely manner or at all; uncertainties as to the timing of the consummation of the Proposed Transaction and the ability of each of CohBar and Morphogenesis to consummate the transactions contemplated by the Proposed Transaction; risks related to CohBar’s and Morphogenesis’ ability to correctly estimate their respective operating expenses and expenses associated with the Proposed Transaction, as applicable, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the resulting combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company’s cash resources; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Proposed Transaction by either company; the effect of the announcement or pendency of the Proposed Transaction on CohBar’s or Morphogenesis’ business relationships, operating results and business generally; costs related to the merger; the outcome of any legal proceedings that may be instituted against CohBar, Morphogenesis, or any of their respective directors or officers related to the merger agreement or the transactions contemplated thereby; the ability of CohBar or Morphogenesis to protect their respective intellectual property rights; competitive responses to the Proposed Transaction; unexpected costs, charges or expenses resulting from the Proposed Transaction; legislative, regulatory, political and economic developments; and additional risks described in the “Risk Factors” section of CohBar’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC. Additional assumptions, risks and uncertainties are described in detail in our registration statements, reports and other filings with the Securities and Exchange Commission and applicable Canadian authorities, which are available on our website, and at www.sec.gov or www.sedar.com.

You are cautioned that such statements are not guarantees of future performance and that our actual results may differ materially from those set forth in the forward-looking statements. The forward-looking statements and other information contained in this news release are made as of the date hereof and CohBar does not undertake any obligation to update publicly or revise any forward-looking statements or information, whether as a result of new information, future events or otherwise, unless so required by applicable securities laws. Nothing herein shall constitute an offer to sell or the solicitation of an offer to buy any securities.

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