

# CohBar Announces Positive Topline Results from the Phase 1a/1b Study of CB4211 Under Development for NASH and Obesity

- CB4211 was well-tolerated and appeared safe with no serious adverse events
- Robust reductions in ALT and AST
- Reduction in glucose and trend towards body weight reduction
- Company to host conference call and webcast at 5:00 p.m. ET

MENLO PARK, Calif., Aug. 10, 2021 (GLOBE NEWSWIRE) -- CohBar, Inc. (NASDAQ: CWBR), a clinical stage biotechnology company developing mitochondria based therapeutics to treat chronic diseases and extend healthy lifespan, today announced topline results from the multi-center, randomized, double-blind, placebo-controlled Phase 1a/1b clinical study of CB4211, under development for nonalcoholic steatohepatitis (NASH) and obesity. The study met its primary endpoint showing that CB4211 was well-tolerated and appeared safe with no serious adverse events. Evaluation of the exploratory pharmacodynamic endpoints from the Phase 1b stage of the study comparing CB4211 to placebo demonstrated robust and significant reductions in key biomarkers of liver damage, ALT and AST, a significant decrease in glucose levels, and a trend towards lower body weight after four weeks of treatment. Both the CB4211 and placebo groups had substantial reductions in liver fat content compared to baseline.

Key findings from the topline data of the Phase 1b portion of the study are summarized below.

Biomarker	CB4211 (25 mg) (n = 11)	Placebo (n = 9)	Difference from Placebo
ALT (% reduction from baseline)	-21%	4%	-25*
Proportion of subjects with >17 U/L decrease in ALT(1)	27%	11%	16%
AST (% reduction from baseline)	-28%	-11%	-17%*
Glucose (% reduction from baseline)	-6%	0%	-6%*

ALT: Alanine aminotransferase. AST: Aspartate aminotransferase.

<sup>\*</sup>Statistically significant versus placebo, p<0.05 by unpaired t test

<sup>(1)</sup> A decrease in ALT by 17 U/L or more is significantly associated with histologic response in NASH (Loomba R et al. Gastroenterology, 2019; 156 (1): 88-95)

MRI-PDFF Data	CB4211 (25 mg) (n = 11)	Placebo (n = 9)
Baseline Liver Fat Content (LFC)	21.1%	15.9%
Percent Reduction in LFC (Absolute)	-5.03%	-4.88%
Proportion of Responders Achieving >30% Relative Reduction in LFC	36%	33%

MRI-PDFF: Magnetic resonance imaging – proton density fat fraction.

"The results from the Phase 1b CB4211 study are promising," stated Dr. Rohit Loomba, MD, MHSc, Professor of Medicine, Director, NAFLD Research Center, and Director of Hepatology, University of California at San Diego. "Demonstrating significant reductions of this magnitude in both serum ALT and AST relative to placebo after only four weeks suggests a potential for improvement in liver health if we continue to see further improvements over a longer period of time in patients with NASH. Improvements in serum ALT and AST are key predictors of histologic response independent of liver fat change; CB4211 shows great promise as a potential candidate for further development in NASH for this growing epidemic of silent and progressive liver disease."

The results from both portions of the study indicate that CB4211 was well-tolerated and appeared safe with no serious adverse events. The only adverse events occurring in >10% of subjects receiving CB4211 in the four-week Phase 1b portion of the study were transient and generally mild to moderate injection site reactions.

"We are pleased with the positive outcome of our first human trial of CB4211 and look forward to working with disease experts to explore the next steps for our CB4211 program," stated Dr. Joseph Sarret, CohBar's Chief Executive Officer. "These impressive results validate our novel approach of using the mitochondrial genome as a valuable source of potential therapeutic peptides to treat serious systemic diseases."

The Phase 1a stage of the study was a double blind, placebo-controlled single ascending dose and multiple ascending dose assessment of safety, tolerability, and pharmacokinetics over one week in 65 healthy adults, to select the most appropriate dose for the Phase 1b stage. The Phase 1b study was a randomized, double-blind, placebo-controlled evaluation of a 25 mg dose of CB4211 given once daily by subcutaneous injection for four weeks in 20 obese subjects with nonalcoholic fatty liver disease (NAFLD). The primary endpoints were safety and tolerability, with a secondary endpoint of pharmacokinetics, and exploratory endpoints of changes in liver fat, body weight, and biomarkers relevant to NASH, obesity, and metabolic disease. Subjects were required to have a minimum of 10% liver fat at enrollment, and to stay in the clinical study unit during the four weeks of treatment. This study was conducted at four sites.

CB4211 is the first mitochondria based therapeutic to enter clinical testing. Mitochondria based therapeutics are an emerging class of drugs based on novel analogs of peptide sequences discovered by CohBar scientists in the mitochondrial genome, some of which

have been shown to have the potential to regulate key processes in multiple systems and organs in the body.

The company is continuing to analyze the data and plans to present additional results and analyses at a future scientific meeting.

#### **Conference Call:**

Date: August 10, 2021

Time: 5:00 p.m. ET (2:00 p.m. PT)

#### Conference Audio

Dial-in U.S. and Canada: (877) 300-8521Dial-in International: (412) 317-6026

• Conference ID No.: 10159293

### Slide Presentation

- Please visit <a href="https://us02web.zoom.us/j/84796437737?">https://us02web.zoom.us/j/84796437737?</a>
   pwd=R2t0eEFRVDVIVDVZMTdhT0pGWVVsUT09 and enter password CWBR, or
- Go to <u>www.cohbar.com</u> and click on CohBar Q2 2021 Investor Presentation at the top of homepage.

For individuals participating in the Investor Call and Slide Presentation, please call into the conference audio and log into Zoom approximately 10 minutes prior to its start. Please note, no audio will be available through Zoom.

An audio replay of the call will be available beginning at 8:00 p.m. Eastern Time on August 10, 2021, through 11:59 p.m. Eastern Time on August 31, 2021. To access the recording please dial (844) 512-2921 in the U.S. and Canada, or (412) 317-6671 internationally, and reference Conference ID# 10159293. The audio recording along with the slide presentation will also be available at <a href="https://www.cohbar.com">www.cohbar.com</a> during the same period.

#### About CB4211

CB4211 is a first-in-class mitochondria based therapeutic (MBT) that recently completed a Phase 1a/1b clinical study for the treatment of nonalcoholic steatohepatitis (NASH) and obesity. CB4211 is a novel and improved analog of MOTS-c, a naturally occurring mitochondrial derived peptide (MDP), which was discovered in 2012 by CohBar founder Dr. Pinchas Cohen and his academic collaborators. NASH has been estimated to affect as many as 30 million adults in the U.S., and there is currently no approved treatment for the disease.

# **About CohBar**

CohBar (NASDAQ: CWBR) is a clinical stage biotechnology company focused on the research and development of mitochondria based therapeutics, an emerging class of drugs for the treatment of chronic and age-related diseases. Mitochondria based therapeutics originate from the discovery by CohBar's founders of a novel group of naturally occurring

peptide sequences within the mitochondrial genome, some of which have been shown to have the potential to regulate key processes in multiple systems and organs in the body. To date, the company has discovered more than 100 mitochondrial derived peptides and generated over 1,000 analogs. CohBar's efforts focus on the development of these peptides into therapeutics that offer the potential to address a broad range of diseases associated with the underlying impact of mitochondrial dysfunction. The company's lead compound, CB4211, recently completed a Phase 1a/1b clinical trial for NASH and obesity. In addition, CohBar has four preclinical programs with the most advanced being CB5138-3 for idiopathic pulmonary fibrosis (IPF) and other fibrotic diseases, which is currently in IND-enabling studies. The preclinical programs also include the CB5064 Analogs for acute respiratory distress syndrome (ARDS) including COVID-19 associated ARDS, CB5046 Analogs for CXCR4-related cancer and orphan diseases, and MBT3 Analogs for cancer immunotherapy.

For additional company information, please visit <u>www.cohbar.com</u>.

# **Forward-Looking Statements**

This news release contains forward-looking statements which 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 statements regarding timing and anticipated outcomes of research and clinical trials for our mitochondria based therapeutic (MBT) candidates: expectations regarding the growth of MBTs as a significant future class of drug products; and statements regarding anticipated therapeutic properties and potential of our mitochondrial peptide analogs, MBTs and other potential therapies. 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: our ability to successfully advance drug discovery and development programs, including the delay or termination of ongoing clinical trials; our possible inability to mitigate the prevalence and/or persistence of the injection site reactions, receipt of unfavorable feedback from regulators regarding the safety or tolerability of CB4211 or the possibility of other developments affecting the viability of CB4211 or CB5138-3 as a clinical candidate or its commercial potential; results that are different from earlier data results including less favorable than and that may not support further clinical development; our ability to raise additional capital when necessary to continue our operations; our ability to recruit and retain key management and scientific personnel; the risk that our intellectual property may not be adequately protected; our ability to establish and maintain partnerships with corporate and industry partners; and risks related to the impact on our business of the COVID-19 pandemic or similar public health crises. 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 securities regulators, 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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