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CohBar Initiates Clinical Study with First-in-human Dosing of CB4211, a Novel Mitochondria Based Therapeutic for the Treatment of NASH

MENLO PARK, Calif., July 12, 2018 (GLOBE NEWSWIRE) -- CohBar, Inc. (NASDAQ:CWBR), a clinical stage biotechnology company developing mitochondria based therapeutics (MBTs) to treat age-related diseases, today announced that it has initiated a Phase 1a/1b safety and biomarker study of CB4211, its lead MBT candidate under development as a potential treatment for non-alcoholic steatohepatitis (NASH) and obesity. CB4211 is the first mitochondria based therapeutic to enter clinical testing.

"The successful completion of our preclinical studies, filing and clearance of the IND, and initiation of this clinical study represent major milestones for the company, as we begin to validate the therapeutic potential of peptides encoded in the mitochondrial genome," said Kenneth C. Cundy, CohBar CSO. "The peptide showed impressive efficacy in preclinical models, and this clinical study is designed to assess safety, as well as to provide an early indication of the therapeutic potential of CB4211 in the setting of NASH and obesity."

The double-blind, placebo-controlled clinical study will initially assess the safety, tolerability, and pharmacokinetics of CB4211 following single and multiple-ascending doses in healthy subjects. The final Phase 1b stage of the study will be an assessment of safety, tolerability, and activity in obese subjects with non-alcoholic fatty liver diseases (NAFLD). Assessments will include changes in liver fat assessed by MRI-PDFF, body weight, and biomarkers relevant to NASH and obesity.

About CB4211

CB4211 is a first-in-class mitochondria based therapeutic that has demonstrated significant therapeutic potential in preclinical models 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 and has been shown to play a significant role in the regulation of metabolism. Data were presented at the 2018 American Diabetes Association meeting providing in vitro evidence that CB4211 inhibits adipocyte lipolysis, a process that is foundational in the development of liver steatosis, through an insulin-dependent mechanism. These data provide a potential mechanistic explanation for previous observations in vivo, including efficacy of CB4211 in animal models of NASH, and anti-steatotic effects on livers of mice on a high fat diet, where a corresponding reduction in circulating fat and biomarkers of liver damage was also observed. The activity of CB4211 appears to be specific to sensitizing insulin action on the insulin receptor. NASH has been

estimated to affect as many as 12% of adults in the U.S. and there is currently no approved treatment for the disease.

About CohBar

CohBar is a clinical stage biotechnology company focused on the research and development of mitochondria based therapeutics (MBTs), an emerging class of drugs for the treatment of age-related diseases. MBTs originate from the discovery by CohBar's founders of a novel group of peptides within the mitochondrial genome which regulate metabolism and cell death, and whose biological activity declines with age. CohBar's efforts focus on the development of these mitochondrial-derived peptides (MDPs) into clinically relevant MBTs that offer the potential to address a broad range of age-related diseases with underlying metabolic dysfunction, including nonalcoholic steatohepatitis (NASH), obesity, Type 2 diabetes, cancer, and cardiovascular and neurodegenerative diseases. To date, the company and its founders have discovered more than 100 MDPs. For additional company information, please visit www.cohbar.com.

Forward-Looking Statements

This news release contains forward-looking statements (statements which are not historical facts) within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include CohBar's plans and expectations for its lead CB4211 drug candidate program, including statements regarding the efficacy, mechanism of action and therapeutic and commercial potential of CB4211 and other mitochondria based therapeutics. Forward-looking statements are based on current expectations, projections and interpretations that involve a number of risks and uncertainties that could cause actual results to differ materially from those anticipated by CohBar. These include uncertainties inherent in research and development, such as the possible inability to complete clinical studies as anticipated, the possibility of unfavorable study results, including unfavorable new data or additional analyses of existing data; risks associated with initial data, including the risk that results of clinical studies may be different from (including less favorable than) those suggested by earlier data results and may not support further clinical development or which otherwise affect the viability or commercial potential of CB4211 or other candidate programs. 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 laws.

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