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CohBar to Resume its Phase 1a/1b Clinical Trial

MENLO PARK, Calif., May 03, 2019 (GLOBE NEWSWIRE) -- CohBar, Inc. (NASDAQ: CWBR), a clinical stage biotechnology company developing mitochondria based therapeutics (MBTs) to treat age-related diseases and extend healthy lifespan, today announced that it has concluded its recent discussions with the FDA and will be resuming its Phase 1a/1b clinical trial of CB4211, its lead MBT candidate under development for the treatment of nonalcoholic steatohepatitis (NASH) and obesity.

“We are working with our clinical partner to resume dosing as soon as possible,” said Philippe Calais, CohBar’s interim CEO. “We are excited to move forward with the clinical evaluation of CB4211, which we believe addresses a foundational event in the etiology of NASH, and as such has the potential to be an important therapeutic option for this increasingly epidemic disease.”

In November 2018, CohBar announced a temporary suspension of the CB4211 Phase 1a/1b study in order to address mild injection site reactions which became unexpectedly persistent. The company subsequently submitted to the FDA related data and documents, including an expert opinion on the absence of a serious safety concern, together with its amended clinical plan designed to address these reactions.

About CB4211

CohBar’s lead program is based on CB4211, a first-in-class mitochondria based therapeutic (MBT) 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. Previously, in July 2018, CB4211 entered a Phase 1a/1b clinical trial which includes a potential activity readout relevant to NASH and obesity. In November 2018, the company announced the temporary suspension of the trial to address mild injection site reactions that were unexpectedly persistent. 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 (NASDAQ: CWBR) 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 suspension of the Phase 1 clinical trial for CB4211, planned steps to address the adverse events and regulatory concerns, suggested causes of injection site reactions and anticipated resumption of the Phase 1 clinical trial for CB4211. 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 the possibility that the Phase 1 clinical trial will remain suspended for longer than anticipated or may not be resumed; CohBar's 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; delays in the resumption of the Phase 1 clinical trial related to CohBar's use of third-party clinical partners or the possibility of other developments affecting the viability of CB4211 as a clinical candidate or its commercial potential. 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, 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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