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CohBar Nominates CB5138 Analog as Lead Clinical Candidate for Idiopathic Pulmonary Fibrosis and other Fibrotic Diseases

MENLO PARK, Calif., March 16, 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 the selection of CB5138-3 as its lead candidate for advancement into IND-enabling activities. CB5138-3 is a CB5138 Analog, a novel class of molecules derived from a natural, mitochondrially encoded peptide source discovered by CohBar, with potential for treatment of Idiopathic Pulmonary Fibrosis (IPF) and other fibrotic diseases. IPF is a chronic, progressive, debilitating and usually fatal interstitial lung disease that affects approximately 100,000 people in the U.S. This orphan disease results in fibrotic scarring of the lungs.

“Nominating our second clinical candidate is an exciting milestone for CohBar and provides additional confirmation of the potential of our novel discovery platform for mitochondria based therapeutics,” stated Steven Engle, CohBar’s Chief Executive Officer. “Our positive preclinical data in models of IPF support the further development of CB5138-3 as a potential antifibrotic and anti-inflammatory therapeutic for IPF, which remains an unmet medical need with few treatment options. Drugs currently approved for IPF can slow the progression of disease but can also cause significant side effects that limit their use. We look forward to the possibility of providing a new treatment option for this devastating disease and exploring the therapeutic potential of CB5138-3 as a treatment of other fibrotic diseases, including other interstitial lung diseases. Fibrotic diseases can affect any organ and are collectively responsible for 45% of deaths in the developed world.”

In the therapeutic mouse model of IPF, multiple CB5138 Analogs demonstrated positive effects on all study outcomes, including reduction of fibrosis, inflammation, and collagen deposition. CohBar also showed enhanced effects for a CB5138 Analog in combination with the standard of care nintedanib, such as greater reduction in fibrosis, inflammation, collagen, and pro-inflammatory cytokines compared to nintedanib alone. CohBar has now completed candidate screening activities and selected CB5138-3 as the lead CB5138 Analog for further development based on its preclinical efficacy data, preliminary safety profile, and drug-like properties.

CohBar will move forward with IND-enabling activities for CB5138-3 with the goal of initiating clinical studies in 2022. In addition, the company is continuing to evaluate the efficacy of the CB5138 Analogs in models of other fibrotic diseases such as NASH, systemic sclerosis, and kidney fibrosis. Fibrosis can occur in the lungs, brain, liver, heart, and other organs.

About CB5138 Analogs

CB5138 Analog peptides are modified analogs of a natural peptide sequence encoded in mitochondrial DNA. Data on the efficacy of CB5138 Analog peptides in preclinical models of IPF were presented at the American Thoracic Society Virtual Annual Meeting in August 2020. In co-cultures of human lung cells, CB5138-1 decreased the expression of key fibrosis biomarkers, including alpha smooth muscle actin (αSMA), and collagen types I and III. CB5138-1 also decreased the transformation of healthy lung cells into fibrotic cells after induction by TGF-beta1, resulting in reduced production of the fibrotic components αSMA and pro-collagen I alpha 1. In vivo, CB5138-1 decreased lung fibrosis and inflammation in both the prophylactic mouse model of IPF, initiating treatment with the peptide immediately after fibrosis induction by bleomycin, and in the therapeutic mouse model of IPF, starting peptide treatment one week after induction. In addition, using the more exacting therapeutic model of IPF, two new analogs of CB5138 (CB5138-2 and CB5138-3) significantly reduced lung fibrosis assessed by the Ashcroft Score, reduced inflammation, and decreased fibrosis-related changes in lung weight, collagen deposition in lung tissue, and collagen secretion into lung fluid.

About IPF & Fibrotic Diseases

Idiopathic Pulmonary Fibrosis (IPF) is a chronic, progressive, debilitating and usually fatal interstitial lung disease that affects approximately 100,000 people in the U.S. This orphan disease results in fibrotic scarring of the lungs. While there are two approved treatments that can help slow the progression of IPF, there is currently no treatment that can stop or reverse the scarring of the lung. Side effects of current approved therapies include gastrointestinal and skin effects.

Early detection of disease is key to slowing progression, while most patients have a three-to-five-year life expectancy. IPF is one example of fibrotic disease. Fibrotic diseases can affect any organ, including liver, kidney, heart, intestines, bone, etc., which together account for 45% of deaths in the developed world.

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, is in the Phase 1b stage of a Phase 1a/1b clinical trial for NASH and obesity. In addition, CohBar has four preclinical programs: CB5138 Analogs for fibrotic diseases, CB5064 Analogs for 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 www.cohbar.com.

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 and statements regarding timing and anticipated therapeutic properties and potential of CB5138-3. 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, research 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 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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