Cerecor Announces Initiation of Phase 2 Clinical Trial With CERC-501 for Smoking Cessation

Cerecor Inc.
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BALTIMORE--(BUSINESS WIRE)--

Cerecor Inc. (CERC), a clinical-stage biopharmaceutical company developing treatments to make a difference in the lives of patients with neurological and psychiatric disorders, today announced that the Company has enrolled its first subject in the Phase 2 clinical trial for CERC-501, *"A Randomized, Double-Blind, Placebo-Controlled, Cross-over Design Study of CERC-501 in a Human Laboratory Model of Smoking Behavior".*

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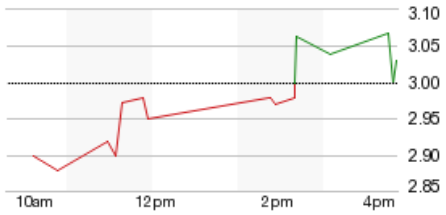

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This is a thirty-day, double-blind, placebo-controlled, crossover study in subjects who are heavy cigarette smokers and currently not seeking treatment for tobacco use disorder. “We are enthusiastic about the potential use of CERC-501 for smoking cessation as well as other addictive disorders,” said Ronald Marcus, M.D., Chief Medical Officer and Head of Regulatory Affairs at Cerecor. The trial design assumes enrollment of 66 subjects who are heavy smokers. In Period 1, half the subjects in each group will receive CERC-501 and the other half will receive placebo. Each subject will then “crossover” to the opposite treatment during Period 2 after a wash-out period. The crossover design allows for subjects to be their own control. The primary objective of the study is to evaluate the effect of CERC-501 compared to placebo on symptoms of tobacco withdrawal and smoking behaviors in subjects who are not seeking treatment for tobacco use disorder. The Company expects to have top-line data in the second half of 2016.

“CERC-501 is selective kappa opioid receptor antagonist that holds the promise to treat a broad range of mood and substance use disorders,” said Uli Hacksell, Ph.D., Cerecor’s CEO, President and Chairman. “For the millions of people who express a desire to reduce, or stop using nicotine, we hope CERC-501 proves to be a safe and effective therapy.”

About CERC-501

CERC-501 is a potent and selective oral kappa opioid receptor, or KOR, antagonist being developed to treat substance use disorders, such as alcohol, nicotine and/or cocaine, and for adjunctive treatment of major depressive disorder (MDD). Kappa opioid receptors have been shown to play an important role in stress, mood and addiction in animal models. CERC-501 has been observed to have positive preclinical activity in models of depression, nicotine withdrawal and alcohol dependence, and it has been generally well tolerated in three human clinical trials.

About Cerecor

Cerecor is a biopharmaceutical company with the goal of becoming a leader in the development of innovative drugs that make a difference in the lives of patients with neurological and psychiatric diseases. We are committed to the development of drugs that improve lives by applying our extensive knowledge and experience in central nervous system disorders. Cerecor is currently pursuing the development of two clinical Phase II-stage product candidates: CERC-301: An oral, NR2B specific, NMDA receptor antagonist targeting the adjunctive treatment of patients with MDD who are failing to achieve adequate response, and CERC-501. In addition Cerecor is conducting preclinical testing of CERC-406, a brain penetrant COMT inhibitor with potential procognitive activity. For more information about the Company and its products, please visit:

www.cerecor.com or contact Mariam E. Morris, Chief Financial Officer, at (443) 304-8002.

Forward-Looking Statements

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