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Cerecor Announces Top-Line Results from CERC-501 Phase 2 Study for Nicotine Withdrawal

BALTIMORE, MD -- (Marketwired) -- 12/05/16 -- Cerecor Inc. (NASDAQ: CERC), a clinical-stage biopharmaceutical company developing treatments to make a difference in the lives of patients with neurological and psychiatric disorders, today announced top-line clinical results from its nicotine withdrawal Phase 2 clinical trial of CERC-501, an oral, potent, and selective kappa opioid receptor ("KOR") antagonist. The trial did not meet its primary objective in nicotine withdrawal. CERC-501 was well tolerated. Based on this favorable side-effect profile, and as previously planned, Cerecor intends to move forward with development of CERC-501 in its primary indication, as an adjunctive treatment of Major Depressive Disorder (MDD).

"While CERC-501 did not demonstrate efficacy in this trial, we are encouraged by the drug's overall safety profile," said Ronald Marcus, M.D., Chief Medical Officer and Head of Regulatory Affairs of Cerecor. "We want to thank the National Institute of Drug Abuse, of the National Institutes of Health, for co-supporting the trial."

The study was a randomized, double-blind, placebo-controlled, crossover study of 71 subjects who are heavy cigarette smokers and currently not seeking treatment for tobacco use disorder. In period one of the study (8 days), half the subjects in each group received 15 mg of CERC-501 and the other half received placebo. Next, "crossover" occurred and subjects received the opposite treatment during period two (8 days), after a one week "wash-out period." The crossover design allowed for subjects to be their own control.

The trial did not achieve its objectives of improvement of CERC-501 compared to placebo on symptoms of tobacco withdrawal and smoking behaviors, as measured by improvement in time to start smoking and number of cigarettes smoked following abstinence.

CERC-501 was generally well-tolerated with no serious adverse events reported and no discontinuations due to adverse events with CERC-501. The most commonly reported adverse events, over 5% and greater than placebo in the study, were diarrhea and decreased appetite.

Cerecor intends to present additional data from this trial at scientific meetings in 2017.

"There is preclinical and recent clinical evidence that strongly support the potential use of other KOR antagonists as novel medicines for the treatment of mood- and stress-related conditions, such as MDD and anxiety disorders. We believe that our KOR antagonist, CERC-501, has similar potential," added Dr. Uli Hacksell, President and Chief Executive Officer at

Cerecor. "We will now turn our focus to preparing CERC-501 for a Phase 2/3 clinical trial as an adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies. We hope to initiate this trial in the second half of 2017."

About CERC-501

CERC-501 is a potent and selective oral KOR antagonist being developed as an adjunctive treatment of MDD and a therapy for substance use disorders. KORs have been shown to play an important role in stress, mood and addiction. CERC-501 has been observed to have positive activity in animal models of depression, substance withdrawal and dependence, and it has been generally well-tolerated in five human clinical trials.

Currently, three externally-funded clinical trials are being conducted to evaluate the use of CERC-501 in treating depressive symptoms, stress-related smoking relapse and cocaine addiction. One study is being conducted under the auspices of the National Institute of Mental Health, the second is a collaboration between Cerecor and Yale University with funding from the National Institutes of Health and the third is being conducted at Rockefeller University Hospital with funding from a private foundation.

The National Institute on Alcohol Abuse and Alcoholism at the National Institutes of Health has given Cerecor a \$1.0 million grant to progress the development of CERC-501 for the treatment of Alcohol Use Disorder ("AUD"). In addition, the Department of Defense has provided research funding to conduct a study of CERC-501 in animal models for co-morbid Post-Traumatic Stress Disorder and AUD.

About Cerecor

Cerecor is a clinical-stage biopharmaceutical company developing innovative drug candidates to make a difference in the lives of patients with neurological and psychiatric disorders. In addition to CERC-501, Cerecor has three other novel compounds in development: CERC-301, CERC-611 and CERC-406.

CERC-301 is an oral, NR2B selective, NMDA receptor antagonist being developed as an adjunctive treatment of MDD. CERC 301 may have the potential to be a first-in-class medication that may significantly reduce depressive symptoms in a matter of days. In a recent Phase 2 trial in MDD, CERC-301 missed the primary endpoint but the 20 mg dose showed signals of efficacy at day 2. Cerecor is continuing to assess the results from this trial and will announce planned next steps at a later date. Cerecor intends to present additional data from this trial at a clinical meeting next year.

CERC-611 is a potent and selective Transmembrane AMPA Receptor Regulatory Proteins ("TARP")- γ 8-dependent α -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid ("AMPA") receptor antagonist, which Cerecor plans to develop as an adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy. Cerecor expects to file an investigational new drug application with the FDA and thereafter, subject to the availability of additional funding, commence Phase 1 development in 2017.

Cerecor has one preclinical stage asset, CERC-406, a brain penetrant catechol-O-methyltransferase inhibitor with potential precognitive activity.

Forward-Looking Statements

This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Cerecor's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Cerecor's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions (including their use in the negative), or by discussions of future matters such as the development of product candidates or products, potential attributes and benefits of product candidates, the expected timing of the commencement of clinical trials, the expected timing of data from clinical trials, and other statements that are not historical. These statements are based upon the current beliefs and expectations of Cerecor's management but are subject to significant risks and uncertainties, including those detailed in Cerecor's filings with the Securities and Exchange Commission. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Cerecor expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Cerecor's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

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