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Cerecor Reports Top-Line Data from CERC-301 Phase 2 Study for Major Depressive Disorder

CERC-301 misses primary endpoint but the 20 mg dose shows clinically meaningful efficacy signals at Day 2; Management to Hold Conference Call and Webcast Today at 5:00 pm ET

BALTIMORE, MD -- (Marketwired) -- 11/29/16 -- 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 major depressive disorder (MDD) Phase 2 clinical trial (Clin301-203) of adjunctive treatment of CERC-301, an oral, NR2B specific, NMDA receptor antagonist. Overall, the trial failed to demonstrate efficacy on the primary endpoint for mean improvement in Bech-6, a subset of the Hamilton Depression Scale (HDRS-17), averaged over days 2 and 4 post dose. However, the study showed signals for the CERC-301 20 mg dose group at Day 2, at pre-specified secondary endpoints, indicating a potentially clinically-meaningful effect, though not statistically significant, on the Bech-6 and HDRS-17.

The trial was a 3-week randomized, double-blind, placebo-controlled, sequential parallel comparison design (SPCD) study of intermittent doses of adjunctive CERC-301 (12 mg or 20 mg) or placebo in the treatment of subjects with MDD who have not adequately responded to antidepressant therapy, either a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine uptake inhibitor (SNRI).

The study randomized 115 subjects. The study was conducted in two sequential one week periods. Placebo non-responders in Period 1 were re-randomized to either study drug or placebo in Period 2. Subjects received treatment at the beginning of each period. The results of Periods 1 and 2 were averaged. The study included a one-week follow-up.

In this SPCD designed study, the mean improvement from baseline on the Bech-6 scale averaged over Days 2 and 4 post treatment for Period 1 was 3.82 for placebo, 2.50 for the 12 mg dose and 4.11 for the 20 mg dose, and for Period 2 was 2.86 for placebo, 1.64 for the 12mg dose and 3.38 for the 20 mg dose. The weighted average for the difference in placebo and drug improvement (placebo minus drug) was +1.45 and -0.04 for 12 mg and 20 mg CERC-301, respectively.

In a pre-specified analysis of the mean improvement from baseline on the Bech-6 at Day 2 for Period 1 was 3.59 for placebo, 4.71 for 20 mg; and for Period 2, 2.30 for placebo and 3.52 for 20 mg. In another pre-specified analysis of the mean improvement from baseline on

the HDRS-17 at Day 2 for Period 1 was 6.24 for placebo and 9.71 for 20 mg; and for Period 2, 3.60 for placebo and 5.38 for 20 mg.

Significant improvement was not observed on the other secondary endpoints evaluated to date.

Consistent with previous trials, CERC-301 was generally well-tolerated with no SAEs reported and no discontinuations due to AEs. The most commonly reported adverse events in the study were increased blood pressure, dizziness, somnolence and paresthesia.

"While the trial failed to achieve the primary efficacy endpoint, we note that these results suggest a potentially clinically meaningful treatment effect in the 20 mg dose at Day 2," added Ronald Marcus, M.D., Chief Medical Officer and Head of Regulatory Affairs at Cerecor.

"Based on this well conducted and controlled clinical trial, we continue to believe that adjunctive CERC-301 may have the potential to reduce depressive symptoms very rapidly with the added patient convenience of oral dosing," said Dr. Uli Hacksell, President and Chief Executive Officer of Cerecor. "We intend to more fully assess the results from this trial as we continue to receive the remaining data sets over the coming weeks and will announce planned next steps for CERC-301 at a later time."

"From a clinician's perspective, these data warrant additional clinical testing to fully explore the potential for this compound to treat MDD," said Dr. Maurizio Fava, Director, Division of Clinical Research of the Massachusetts General Hospital Research Institute & Executive Vice Chair, Department of Psychiatry. "I would note that a minimum of 2 points of improvement on the HDRS-17 scale compared to placebo is considered by many, and noted in MDD studies, to be clinically meaningful."

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

Conference Call

Cerecor's management team will host a conference call and webcast today, November 29, 2016 at 5:00 p.m. ET to discuss these top-line results. Presentation slides will be available via the webcast link. A question and answer session will follow Management's remarks. To participate on the live call, please dial 877-407-2985 (domestic) or +1-201-378-4915 (international), approximately 5 to 10 minutes ahead of the start of the call.

A live audio webcast of the call will be available via the "Investor Relations" page of the Cerecor website, www.cerecor.com. Please log on through Cerecor's website approximately 10 minutes prior to the scheduled start time. A replay of the webcast will be archived on Cerecor's website for 90 days following the call.

About CERC-301

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. Based on the signal of potential clinical meaningfulness shown in Phase 2 testing, we are currently assessing future development.

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-301, Cerecor is currently pursuing the development of CERC-501, which is also a clinical Phase 2-stage product candidate, as well as two earlier stage programs.

CERC-501 is a potent and selective kappa opioid receptor antagonist that is currently in a Phase 2 clinical trial for smoking cessation that is expected to provide top-line data in December 2016. In addition to Cerecor's Phase 2 trial, 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. Cerecor intends to begin Phase 2 testing of CERC-501 for the treatment of adjunctive MDD.

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 we plan to develop as an adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy. We expect to file an investigational new drug application with the FDA and thereafter commence Phase 1 development in 2017.

Cerecor's brain penetrant catechol-O-methyltransferase inhibitors, including CERC-406, are in preclinical development and may have potential procognitive 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 benefits of product candidates, the expected timing of the commencement of clinical trials, the expected timing of data from clinical trials, technology enhancements 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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