July 1, 2019

Cerecor Announces Positive Final Results of CERC-301 in the Treatment of Neurogenic Orthostatic Hypotension (OH)

ROCKVILLE, Md., July 01, 2019 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases in pediatrics and neurology, today announced positive results from its completed Phase I study of CERC-301, being developed for the treatment of neurogenic orthostatic hypotension (nOH). These final results further strengthen the previously reported interim results, showing that CERC-301 produces a rapid, robust and sustained improvement in systolic blood pressure (SBP) upon standing in Parkinson's patients suffering from nOH, utilizing the standardized Orthostatic Standing Test (OST).

The final data continue to reinforce the rapid, robust and sustained increase in SBP upon standing as early as one-hour post dose that continued across the 6-hour study period. The highest dose tested, 20mg, achieved clinically meaningful (>7 mmHg SBP) improvements throughout the study over baseline and placebo with a maximum improvement of 29.1 mmHg, consistent with the interim analysis. This early and sustained effect could differentiate CERC-301 from existing nOH treatments. There were no serious adverse events and all doses were considered safe and well tolerated.

"*We believe these results further strengthen the data package we are building for this compound to treat patients suffering from neurogenic orthostatic hypotension. Prior to initiating the study, we knew CERC-301 had vasopressor characteristics in normotensive patients and volunteers. These results validate our hypothesis that CERC-301 improves hypotension (low blood pressure) in patients with OH associated with neurodegenerative diseases, such as Parkinson's. We are excited to move the development of this compound forward and broaden its clinical utility in other conditions associated with OH",* stated Dr. Perry Calias, Ph.D., Cerecor CSO.

Dr. Stuart Isaacson, Director, Parkinson's Disease and Movement Disorders Center of Boca Raton, Associate Professor of Neurology, Herbert Wertheim College of Medicine and the Study's Lead Investigator, noted, *"These robust and sustained blood pressure results make CERC-301 an exciting and promising compound for the treatment of nOH. The fact that these improvements in blood pressure upon standing are seen at least to, and perhaps beyond, six hours post dose may represent a significant step forward in novel treatment options for patients suffering from the debilitating symptoms of nOH."*

About CERC-301

CERC-301 is an orally available, NR2B-specific, NMDA receptor antagonist being developed for the treatment of symptomatic OH. NMDA receptor overactivation is associated with many neurodegenerative diseases, including Parkinson's disease.

About the Study

This was a Phase I, single escalating dose, placebo-controlled study to assess the safety, tolerability, and pharmacodynamics of CERC-301 enrolled 19 patients with nOH associated with Parkinson's disease of which 14 were randomized. Enrollment was closed following the positive interim results seen in April 2019. Patients were randomized to one of four treatment arms where they received single escalating doses of CERC-301 at 8 mg, 12 mg, 16 mg, or placebo over 4 study visits. All patients received placebo during at-least one study visit. Patients returned for a fifth study visit and were randomized again to receive either CERC-301 at a dose of 20 mg or placebo. At each visit, patients completed Orthostatic Standing Test (OSTs) at pre-dose, 1, 2, 3, 4 and 6 hours post-dose.

The Orthostatic Standing Test is a standardized procedure whereby patients lay semi-supine (head up 30 degrees) for 10 minutes prior to standing then stand for 5 minutes. Blood pressure and heart rate measurements were taken in a seated position before lying down and then at -10 minutes, -5 minutes and immediately prior to standing then again at +1, +3 and +5 minutes after standing. A final seated blood pressure reading was recorded after completion of the 5-minute standing period.

About Orthostatic Hypotension (OH)

Orthostatic hypotension is a sudden fall in blood pressure that occurs when a person assumes a standing position. It is due to a lesion of the baroreflex loop, which senses a change in blood pressure and adjusts heart rate and activates sympathetic nerve system fibers to cause the blood vessels to narrow and correct blood pressure. It may also be caused by hypovolemia (a decreased amount of blood in the body), resulting from the excessive use of diuretics, vasodilators, or other types of drugs, dehydration, or prolonged bed rest. The disorder may be associated with Addison's disease, diabetes, spinal cord injuries, dialysis, advanced age and certain neurological disorders including Multiple System Atrophy with Orthostatic Hypotension (formerly known as Shy-Drager syndrome), autonomic system neuropathies, and other dysautonomias. Symptoms, which generally occur after sudden standing, include dizziness, lightheadedness, blurred vision, and syncope (temporary loss of consciousness).

Current treatment options for OH target symptom burden reductions to increase quality of life such as correcting aggravating factors (i.e. discontinuation of hypotension drugs and correction of anemia and vitamin deficiencies); nonpharmacologic measures such as intravascular volume expansion, increased physical activity, reduction of meal size, compression stocking/abdominal binder, and sleeping arrangement; and drug therapies (i.e. droxidopa, midrodrine).

About Cerecor

Cerecor is a fully integrated biopharmaceutical company with commercial operations and research and development capabilities. The Company is building a robust pipeline of innovative therapies in orphan rare diseases, neurology and pediatric healthcare. The

Company's pediatric orphan rare disease pipeline is led by CERC-801, CERC-802 and CERC-803 ("CERC-800 programs"), which are therapies for inborn errors of metabolism specifically disorders known as Congenital Disorders of Glycosylation. The FDA granted Rare Disease Designation and Orphan Drug Designation to all three CERC-800 compounds, thus qualifying them for receipt of a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The PRV may be sold or transferred an unlimited number of times. The Company plans to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate development and approval. The Company is also in the process of developing one other preclinical pediatric orphan rare disease compound for the treatment of mitochondrial DNA Depletion Syndrome. The Company's neurology pipeline is led by CERC-301, which Cerecor is currently exploring as a novel treatment for neurogenic orthostatic hypotension. The Company is also developing two other neurological compounds; CERC-406 for Parkinson's Disease, CERC-611 for epilepsy. The Company also has a diverse portfolio of marketed products. Our marketed products are led by our prescribed dietary supplements and prescribed drugs. Our prescribed dietary supplements include Poly-Vi-Flor® and Tri-Vi-Flor™ which are prescription vitamin and fluoride supplements used in infants and children to treat or prevent deficiency of essential vitamins and fluoride. The Company also markets a number of prescription drugs that treat a range of pediatric diseases, disorders and conditions. Cerecor's prescription drugs include AcipHex®, Cefaclor for Oral Suspension, Karbinal™ ER, Sprinkle™, Millipred® and Ulesfia®.

For more information about Cerecor, please visitwww.cerecor.com.

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; timing and success of trial results and regulatory review (including as it may be impacted by government shut-downs); potential attributes and benefits of product candidates; the expansion of Cerecor's drug portfolio; 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: drug development costs, timing and other risks; reliance on and the need to attract, integrate and retain key personnel; Cerecor's cash position and the potential need for it to raise additional capital; risks associated with acquisitions, including the need to quickly and successfully integrate acquired assets and personnel; and those other risks 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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Source: Cerecor Inc.