

# Cerecor Announces First Patient Enrolled in Multicenter Proof-of-Concept Study Evaluating CERC-002 for COVID-19 ARDS

# **Top-line Data Anticipated in Fourth Quarter 2020**

ROCKVILLE, Md., July 21, 2020 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in the development and commercialization of treatments for rare pediatric and orphan diseases, today announced the first patient has been enrolled in a proof-of-concept trial evaluating the safety and efficacy of the anti-LIGHT monoclonal antibody, CERC-002, in patients with COVID-19 cytokine storm-induced Acute Respiratory Distress Syndrome (ARDS).

The proof-of-concept, randomized, multicenter, double-blind, placebo-controlled trial will enroll approximately 82 subjects hospitalized with COVID-19 ARDS. The primary objective of the study is to demonstrate that treatment with CERC-002 results in fewer instances of respiratory failure and death versus the standard of care. Patients in the CERC-002 arm will receive a single dose of drug and be followed for 28 days. Key secondary endpoints include intensive care unit (ICU) length of stay, hospital length of stay, and oxygen saturation at the end of the study. Top-line data are expected in the fourth quarter of 2020.

"We believe that suppressing levels of the inflammatory cytokine LIGHT, which is associated with increased morbidity and mortality in ventilated COVID-19 patients, might dampen the cytokine storm and prevent severe ARDS in this population," said H. Jeffrey Wilkins, MD, Chief Medical Officer of Cerecor. "As the first and only fully human anti-LIGHT monoclonal antibody, we believe CERC-002 has the potential to treat patients hospitalized with COVID-19 ARDS. Our collaboration with PRA Health Sciences – a contract research organization and healthcare intelligence partner – has helped us to rapidly identify, recruit and initiate key centers to expedite the study. Both organizations look forward to advancing this program, as we strive to provide an effective therapeutic option for hospitalized COVID-19 patients to keep them from progressing to ARDS."

The scientific rationale for the study is supported by positive results from Cerecor's and Myriad Genetics' recent biomarker study, conducted with Hackensack Meridian Health Network, which demonstrated elevated levels of the inflammatory cytokine LIGHT in patients hospitalized with COVID-19 cytokine storm-induced ARDS. In the patients studied, LIGHT levels were significantly elevated in the serum of hospitalized patients with COVID-19 versus healthy controls (p value < 0.0001). The highest LIGHT levels were found in patients who required ventilator support, particularly in patients over 60 years of age. Importantly, the data demonstrated elevated LIGHT levels were also strongly linked with mortality (p=0.02). The data suggest that LIGHT might play a key role in cytokine storm that leads to ARDS. CERC-

002 is a first-in-class monoclonal antibody targeted against the inflammatory cytokine LIGHT. It is the only anti-LIGHT therapy in clinical development and has the potential to be a treatment option for this patient population in critical need.

# **CERC-002** (anti-LIGHT monoclonal antibody)

CERC-002 is an anti-LIGHT (part of the Tumor Necrosis Super Family 14) fully human monoclonal antibody licensed from Kyowa Kirin Co., Ltd. in the clinic. It offers the potential to treat cytokine storm-induced COVID-19 ARDS in the near-term and broader ARDS indication beyond. It is currently being developed as a treatment for Pediatric Crohn's Disease and now cytokine storm induced COVID-19 ARDS. Cerecor has also developed a validated serum/plasma free LIGHT assay in collaboration with Myriad RBM. This assay has shown to have high sensitivity and specificity for free LIGHT which has been shown to be elevated in patients with active Crohn's disease and with COVID-19 related ARDS.

# Role of LIGHT in Acute Inflammatory Response

LIGHT (homologous to Lymphotoxin, exhibits inducible expression and competes with HSV glycoprotein D for binding to herpesvirus entry mediator, a receptor expressed on T lymphocytes) is a cytokine with inflammatory actions encoded by the TNFSF14 gene. LIGHT has been shown to play a key role in the immune response to viral pneumonia. LIGHT plays an important role in regulating immune responses in the lung, gut and skin. It stimulates T Cell and B Cell response as well as induces the release of other cytokines such as IL1, IL6, IL-8, IL-10, TNF and GM-CSF.

### **About Cerecor**

Cerecor is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies. The Company's pediatric 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 ("CDGs"). The FDA granted Rare Pediatric Disease Designation and Orphan Drug Designation ("ODD") to all three CERC-800 programs, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as Adult Onset Stills Disease ("AOSD") and Multiple Myeloma ("MM"). CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex Lymphatic Malformations. CERC-002 is an anti-LIGHT monoclonal antibody being developed for the treatment of COVID-19 ARDS and Pediatric-onset Crohn's Disease.

For more information about Cerecor, please visit<u>www.cerecor.com</u>.

### **About PRA Health Sciences**

PRA Health Sciences is one of the world's leading global contract research organizations by revenue, providing outsourced clinical development and data solution services to the biotechnology and pharmaceutical industries. PRA's global clinical development platform

includes more than 75 offices across North America, Europe, Asia, Latin America, South Africa, Australia, and the Middle East and more than 17,500 employees worldwide. Since 2000, PRA has participated in approximately 4,000 clinical trials worldwide. In addition, PRA has participated in the pivotal or supportive trials that led to U.S. Food and Drug Administration or international regulatory approval of more than 95 drugs. To learn more about PRA, please visit www.prahs.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," "might," "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; potential attributes and benefits of product candidates; 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, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; regulatory risks; Cerecor's cash position and the need for it to raise additional capital; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic; 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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