

# Cerecor Resumes Phase 1b Clinical Trial of CERC-002 for the Treatment of Severe Pediatric Onset Crohn's Disease

ROCKVILLE, Md. and CHESTERBROOK, Pa., Aug. 26, 2020 (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, today announced it has resumed the Phase 1b clinical study of CERC-002 in anti-TNF refractory adult Crohn's patients with the lifting of the moratorium on elective endoscopy resulting from the COVID-19 pandemic. CERC-002 is a first-in-class fully human anti-LIGHT (TNFSF14) monoclonal antibody currently being developed as a treatment for severe pediatric onset Crohn's disease as well as in a placebo-controlled proof-of-concept trial evaluating the safety and efficacy in patients with COVID-19 cytokine storm-induced Acute Respiratory Distress Syndrome (ARDS).

The open-label, dose-escalating, signal-finding Phase 1b clinical study is designed to assess the safety, tolerability, and short-term efficacy of CERC-002 in adult subjects with moderate-to-severe Crohn's disease who have previously failed treatment with anti-TNF agents. The Company expects to announce topline data in the first quarter of 2021.

"We are excited to now have two active clinical studies evaluating the safety and efficacy of the anti-LIGHT monoclonal antibody, CERC-002," stated Dr. H. Jeffery Wilkins, chief medical officer at Cerecor. "There has been an increasing level of scientific evidence supporting the rationale behind LIGHT being a key target for immune conditions of the mucosa of the lung and gut. We believe CERC-002 may have the potential to treat both patients with Crohn's disease refractory to biologics and patients with COVID-19 ARDS, both of which lack effective treatment options."

# 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 Tumor Necrosis Factor Super Family 14 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 and gut. It stimulates T Cell and B Cell response as well as induces the release of other cytokines such as IL-1, IL-6, IL-8, IL-10, TNFs and GM-CSF.

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

CERC-002 is a first in class fully human anti-LIGHT (TNFSF14) monoclonal antibody

licensed from Kyowa Kirin Co., Ltd. It offers the potential to treat cytokine release syndrome-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 release syndrome 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.

#### **About Cerecor**

Cerecor is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases. The company is advancing its clinical-stage pipeline of innovative therapies that address unmet patient needs within rare and orphan diseases. The company's rare disease pipeline includes CERC-801, CERC-802 and CERC-803 ("CERC-800 compounds"), which are therapies for inherited metabolic disorders known as congenital disorders of glycosylation. The U.S. Food and Drug Administration ("FDA") granted Rare Pediatric Disease Designation ("RPDD") and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus potentially qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of each new drug application ("NDA"). The company is also developing CERC-002, CERC-006 and CERC-007. CERC-002 is an anti-LIGHT monoclonal antibody being developed for the treatment of severe pediatric-onset Crohn's disease, and is also in clinical trial for COVID-19 acute respiratory distress syndrome. CERC-006 is a dual mTOR inhibitor being developed for the treatment of complex lymphatic malformations and has been granted ODD and RPDD by the FDA, thus potentially qualifying the company to receive a fourth PRV upon approval of an NDA. CERC-007 is an anti-IL-18 monoclonal antibody being developed for the treatment of autoimmune inflammatory diseases such as adult onset Stills disease and multiple myeloma.

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," "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 potential 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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