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Cerecor Announces FDA Clearance of IND for CERC-002 in COVID-19 Induced ARDS

Company to Initiate Multicenter, Placebo-controlled, Randomized Study in June
Top-line Data Anticipated in Fourth Quarter 2020

ROCKVILLE, Md., May 28, 2020 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to proceed with a proof-of-concept clinical trial of its anti-LIGHT monoclonal antibody CERC-002 in patients with COVID-19 cytokine storm induced Acute Respiratory Distress Syndrome (ARDS). The study will assess the efficacy and safety of CERC-002. The first patient is expected to enroll in June and top-line data are expected in the fourth quarter of 2020.

The randomized, multi-center, 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 ICU length of stay, hospital length of stay and oxygen saturation at the end of study.

The scientific rationale for the study was driven by positive results from a recent biomarker study conducted with Hackensack Meridian Health Network demonstrating 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 may 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.

Cerecor's chief medical officer, Dr. H. Jeffrey Wilkins stated,*"There is an urgent need for therapies to help patients with COVID-19 ARDS given the ongoing spread of the SARS-CoV-2 and limited therapeutic options. With FDA clearance, we plan to initiate a clinical trial to evaluate anti-LIGHT antibody therapy in patients with COVID-19 cytokine storm-induced ARDS. The trial is designed to generate rapid and definitive results in the fourth quarter of 2020."*

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 **L**ymphotoxin, exhibits **i**nducible expression and competes with HSV **g**lycoprotein D for binding to **h**erpesvirus 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 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 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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