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# FDA Grants Fast Track Designation to CERC-002 for Treatment of Hospitalized Patients with COVID-19

ROCKVILLE, Md. and CHESTERBROOK, Pa., May 11, 2021 (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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to CERC-002 for treatment of hospitalized patients with COVID-19. CERC-002 is a first-in-class fully human monoclonal antibody targeting LIGHT (tumor necrosis factor superfamily member 14, TNFSF14).

Fast Track designation is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the provision is to help facilitate development and expedite the review of drugs to treat serious or life-threatening conditions so that an approved product can reach the market expeditiously. Sponsors of drugs that receive Fast Track designation have the opportunity for more frequent interactions with the FDA review team throughout the development program. Under Fast Track designation, a Biologic License Application (BLA) for CERC-002 is eligible for both rolling submission and priority review.<sup>1</sup>

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

CERC-002 is a fully human anti-LIGHT or tumor necrosis factor superfamily member 14 (TNFSF14) monoclonal antibody licensed from Kyowa Kirin Co., Ltd. It is the only clinical stage anti-LIGHT therapy and has the potential to treat a number of LIGHT-associated immune diseases including cytokine storm-induced COVID-19 ARDS. It is currently in development for pediatric onset Crohn's disease and cytokine storm induced COVID-19 ARDS. Cerecor has also developed a validated, high sensitivity serum/plasma free LIGHT assay in collaboration with Myriad RBM.

## **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 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 IL-1, IL-6, IL-8, IL-10, TNF and GM-CSF. Therefore, LIGHT potentially plays a key role in immune responses to viral pneumonia and other diseases.

## **About Cerecor**

Cerecor is a biopharmaceutical company focused on becoming a leader in the 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, which are in development for congenital disorders of glycosylation and CERC-006, an oral mTORc1/c2 inhibitor in development for the treatment of complex lymphatic malformations. The company is also developing two monoclonal antibodies, CERC-002, and CERC-007. CERC-002 targets the cytokine LIGHT (TNFSF14) and is in clinical development for treatment of severe pediatric-onset Crohn's disease, and COVID-19 acute respiratory distress syndrome. CERC-007 targets the cytokine IL-18 and is in clinical development for the treatment of Still's disease (adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)), and multiple myeloma (MM). CERC-006, 801, 802 and 803 have all received Orphan Drug Designation and Rare Pediatric Disease Designation, which makes all four eligible for a priority review voucher upon FDA approval.

For more information about Cerecor, please visit [www.cerecor.com](http://www.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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<sup>1</sup> <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm>



Source: Cerecor Inc.