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Cerecor Announces FDA Acceptance of Investigational New Drug Application for CERC-803 to Treat Leukocyte Adhesion Deficiency Type II

ROCKVILLE, Md. and CHESTERBROOK, Pa., Dec. 01, 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 that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug Application (IND) to study the use of CERC-803 to treat Leukocyte Adhesion Deficiency Type II (LAD II). The company plans to initiate a pivotal trial of CERC-803 in LAD-II (SLC35C1-CDG) by the first half of 2021 and anticipates topline data in the second half of 2021.

"There are currently no FDA-approved therapies for patients suffering from LAD-II" said H. Jeffrey Wilkins, MD, Chief Medical Officer of Cerecor. *"LAD-II is caused by genetic mutations that result in deficiency in expression of surface adhesion molecule selectin, leading to defective leukocyte functions. This is a pediatric disease with the first symptoms appearing in infancy with recurrent bacterial infections, growth retardation, facial dysmorphism, and severe intellectual deficit as they continue to grow. We are excited to advance this program into the clinic."*

The FDA granted Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) to CERC-803, thus potentially qualifying the Company to receive a Priority Review Voucher (PRV) upon approval of a new drug application (NDA).

About CERC-800s
CERC-801, CERC-802 and CERC-803 are monosaccharide therapies with known therapeutic utility for the treatment of select congenital disorders of glycosylation (CDGs). Oral administration at therapeutic doses of CERC-801, CERC-802, and CERC-803 replenishes critical metabolic intermediates that are reduced or absent due to genetic mutation, overcoming single enzyme defects in respective CDGs to support glycoprotein synthesis, maintenance and function.

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 (CERC-800 compounds), which are therapies for inherited

metabolic disorders known as congenital disorders of glycosylation. The FDA granted RPDD and ODD to all three CERC-800 compounds, thus potentially qualifying the Company to receive a PRV upon approval of each 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 being studied 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 Still's disease and multiple myeloma.

For more information about Cerecor, please visit 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.

For media and investor inquiries

James Harrell
Investor Relations
Chief Commercial Officer
Cerecor Inc.
jharrell@cerecor.com
623.439.2220 *office*

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