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Cerecor Announces Fast Track Designation for CERC-803 for the Treatment of Leukocyte Adhesion Deficiency Type II

ROCKVILLE, Md., Feb. 02, 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-803 for the treatment of Leukocyte Adhesion Deficiency Type II (LAD-II, also known as SLC35C1-CDG). The company remains on track to initiate a pivotal trial of CERC-803 in LAD-II in the first half of 2021 and anticipates topline data in the second half of 2021.

"We are excited to receive Fast Track Designation for CERC-803 to treat LAD-II," said H. Jeffrey Wilkins, MD, Chief Medical Officer of Cerecor. *"LAD-II is a serious and life-threatening ultra-rare disease caused by genetic mutations resulting in hypotonia, failure to thrive, and increased susceptibility to developing recurrent bacterial and fungal infections. Many patients also have significant life-threatening bleeding disorders. There are currently no FDA-approved therapies for patients suffering from LAD-II. Fast Track Designation offers us broader access to the FDA and an expedited review process, giving us the potential for accelerated approval to bring a much-needed therapy for patients with LAD-II."*

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.

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, 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.

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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