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FDA Grants Cerecor's Three Substrate Replacement Therapies Orphan Drug Designation

BALTIMORE, Jan. 16, 2019 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of therapies for rare and orphan diseases in pediatrics and neurology, announced today that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designations (ODD) to Cerecor's three substrate replacement therapies for Congenital Disorders of Glycosylation (CDGs).

The FDA granted ODD to: CERC-801, D-galactose for the treatment of Phosphoglucomutase 1 (PGM1) Deficiency; CERC-802, D-mannose for the treatment of Mannose Phosphate Isomerase (MPI) Deficiency; and CERC-803, L-fucose for the treatment of Congenital Disorder of Glycosylation IIc (CDG-IIc).

Each indication is an ultra-rare CDG estimated to have fewer than 1,000 patients in the United States. All three programs have previously been granted Rare Pediatric Disease Designation (RPDD) by the FDA. Cerecor completed pre-IND meetings with the FDA and seeks to leverage the 505(b)(2) pathway to expedite approval of each product.

Peter Greenleaf, Cerecor's CEO, stated, *"We are proud and excited to be a leader in CDG drug development. We've advanced the development of each program on multiple fronts and we look forward to continued progress in our collaborations with researchers, physicians and, most importantly, patients. Our goal is to put these therapies in the hands of patients and their caregivers, and we hope the 505(b)(2) pathway continues to provide flexibility and acceleration of these efforts."*

There are numerous benefits associated with receipt of both ODD and RPDD, including:

-7-year marketing exclusivity (upon approval) in the United States;
-Tax credits (up to 25% of clinical development costs);
-Waiver of PDUFA Application Fees (filing fees); and
-Rare Pediatric Disease Priority Review Voucher (upon approval) for each compound that has been granted RPDD

About CDG:
CDGs are a rapidly expanding group of rare Inborn Errors of Metabolism (IEMs) due to defects in glycosylation. Glycosylation is the process by which carbohydrate complexes are created, modified and attached to proteins and lipids, creating glycoconjugates that are essential for cell structure and function in all tissues and organs. CDG is caused by a specific

inherited mutation and more than 100 CDGs have been identified to date. CDGs typically present in infancy and can be associated with a broad spectrum of symptoms that include severe, disabling or life-threatening cases.

About CERC Compounds for CDG:
CERC-801, CERC-802 and CERC-803 represent monosaccharide substrate replacement therapies with established therapeutic utility for the treatment of CDGs. Oral administration of these substrates replenishes critical metabolic intermediates that are reduced or absent due to genetic mutation, overcoming single enzyme defects to support glycoprotein synthesis, maintenance and function.

About Cerecor
Cerecor is a biopharmaceutical company focused on becoming a leader in the development of orphan neurologic and pediatric therapies that make a difference in the lives of patients. The Company's pipeline is led by CERC-301, which Cerecor is currently exploring as a novel treatment for neurogenic orthostatic hypotension. Cerecor has six additional programs in development, including CERC-406 for Parkinson's Disease, CERC-611 for epilepsy, CERC-801, CERC-802, and CERC 803 for Congenital Disorders of Glycosylation and CERC-913 for DGUOK Deficiency a mitochondrial DNA Depletion Syndrome. The Company's R&D efforts are supported by revenue from its franchise of commercial medications led by Poly-Vi-Flor® and Tri-Vi-Flor® (multivitamin and fluoride supplement tablet, chewable and suspension/drops). In February 2018, the Company added to its marketed product portfolio by acquiring Karbinal™ ER, AcipHex® Sprinkle™, Cefaclor for Oral Suspension, and Flexichamber™.

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," "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 (including as it may be impacted by government shut-downs) potential attributes and benefits of product candidates; the expansion of Cerecor's drug portfolio; 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; Cerecor's cash position and the potential need for it to raise additional capital; risks associated with acquisitions, including the need to quickly and successfully integrate acquired assets and personnel; 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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