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Cerecor Receives Rare Pediatric Disease Designation for CERC-801 for Patients with Inborn Error of Metabolism

BALTIMORE, Oct. 30, 2018 (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 in pediatrics and neurology, announced today that it has been awarded Rare Pediatric Disease Designation (RPDD) from the U.S. Food and Drug Administration (FDA) for CERC-801.

CERC-801 is a substrate replacement therapy to treat an ultra-rare inherited metabolic disorder known as an Inborn Error of Metabolism (IEM). CERC-801 was originally developed by Ichorion, which Cerecor acquired in September 2018.

Peter Greenleaf, Cerecor CEO, commented, *"We are excited by the rapid response from the FDA and its recognition of the need for therapies for patients suffering from these serious and life-threatening disorders with no approved treatment. This decision from the FDA further reinforces our recent Ichorion acquisition, which helped us aggressively accelerate value creation by continuing to build our pipeline and overall transformation strategy for the organization."*

The FDA grants RPDD to programs addressing rare diseases or conditions that are serious or life-threatening in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents. The term "rare disease or condition" means any disease or conditions affecting less than 200,000 people in the United States. If a new drug application (NDA) for CERC-801 is approved, Cerecor is eligible to receive a priority review voucher for another compound, which it could use itself, or sell to another company.

About Inborn Errors of Metabolism

Inborn Errors of Metabolism form a large class of genetic diseases involving congenital disorders of metabolism. The majority are due to defects of single genes that code for enzymes that facilitate conversion of substrates into products and/or intermediates. In most cases, issues arise due to accumulation of substances that are toxic or interfere with normal function, or due to the effects of reduced ability to synthesize essential compounds.

About CERC-801

CERC-801 is a genetically-targeted, substrate replacement therapy used to treat an ultra-rare inherited metabolic disorder that belongs to a class of Inborn Errors of Metabolism (IEMs).

About Cerecor

Cerecor is a biopharmaceutical company focused on becoming a leader in the development of 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 orphan neurological indications. Cerecor is also developing three pre-clinical stage compounds, CERC-611, CERC-406 and CERC-913. The Company's R&D efforts are supported by revenue from its franchise of commercial medications led by Poly-Vi-Flor® (multivitamin and fluoride supplement tablet, chewable) and Tri-Vi-Flor® (multivitamin and fluoride supplement 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 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," "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; 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.

For media and investor inquiries

John Woolford
Westwicke Partners
john.woolford@westwicke.com
443-213-0506 *office*
410-375-3658



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