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Cerecor Announces FDA Acceptance of Investigational New Drug Application for CERC-007 for the Treatment of Still's Disease

ROCKVILLE, Md. and CHESTERBROOK, Pa., Dec. 22, 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 its Investigational New Drug Application (IND) to study the use of CERC-007 to treat Still's disease has been accepted by the United States Food and Drug Administration (FDA) and is now open. CERC-007 is a high affinity, fully human anti-IL-18 monoclonal antibody (mAb). The first study will be a global multicenter Phase 1b clinical trial in adult onset Still's disease and is planned to start in the first quarter of 2021. Initial data is expected in the second quarter of 2021.

"Adult onset Still's disease (AOSD) is a rare inflammatory disease resulting in joint damage, high fever and rashes," said H. Jeffrey Wilkins, MD, Chief Medical Officer of Cerecor.*"The hallmark of AOSD is elevated IL-18 levels. Targeting IL-18 using CERC-007 is a novel therapeutic approach for the treatment of AOSD."*

The planned Phase 1b clinical trial will be a global multi-center, open-label trial of CERC-007 that will enroll approximately 12 subjects with active AOSD. The primary objectives of the study will be to determine the safety and tolerability of CERC-007, and assess preliminary efficacy as measured by reductions in systemic clinical manifestations and markers of inflammation in subjects with AOSD.

About Still's disease
Still's disease is a serious and rare auto-inflammatory disorder that affects the entire body. There are two major forms of the disease: adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA). AOSD and sJIA share common clinical manifestations, including episodes of high, spiking fevers, rash, joint pain, muscle pain, sore throat, multiorgan involvement and elevated levels of IL-18.

About CERC-007
CERC-007 is a high affinity, fully human monoclonal antibody targeting the proinflammatory cytokine IL-18. It is in development for multiple auto-immune diseases, including Still's disease (adult onset Still's disease (AOSD) and systemic juvenile idiopathic arthritis (sJIA)), and multiple myeloma (MM).

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 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," "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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