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# Cerecor Announces FDA Acceptance of Investigational New Drug Application for CERC-007 for Treatment of Relapsed or Refractory Multiple Myeloma

ROCKVILLE, Md. and CHESTERBROOK, Pa., Dec. 08, 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 relapsed or refractory multiple myeloma (MM) has been accepted by the United States Food and Drug Administration (FDA) and is now open. The first study will be a U.S. multicenter Phase 1b clinical trial. Initial data is expected in the first quarter of 2021.

*“Elevated levels of IL-18 are correlated with poor survival in patients with multiple myeloma<sup>1</sup>,”* said H. Jeffrey Wilkins, MD, Chief Medical Officer of Cerecor. *“Targeting and reducing IL-18 using CERC-007 may substantially benefit relapsed or refractory multiple myeloma patients. Our first study under this new IND will give us important information about the pharmacokinetics, pharmacodynamics, dose, safety and preliminary efficacy that should illuminate the path forward. We look forward to sharing the data with the scientific and medical communities in the first quarter of 2021.”*

The planned Phase 1b clinical trial is a U.S. multicenter, open-label, dose-escalation, sequential group study of CERC-007 as a monotherapy in approximately 30 patients with relapsed or refractory MM. The primary objectives of the study will be to determine the safety and tolerability of CERC-007, the recommended Phase 2 dose, and preliminary efficacy as measured by response rate in accordance with International Myeloma Working Group (IMWG) criteria.

## **About Multiple Myeloma**

Multiple myeloma is the second most common blood cancer, with approximately 140,000 patients in the United States.<sup>2</sup> Multiple myeloma is characterized by an excess proliferation of plasma cells. Despite increased availability of new agents, the disease is characterized by a pattern of recurrent relapses and remains incurable for the majority of patients, with a 5-year survival rate of approximately 50%.<sup>2</sup>

## **About CERC-007**

CERC-007 is a 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 visit [www.cerecor.com](http://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**

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<sup>1</sup>Nakamura K, Kassem S, Cleynen A et al. *Cancer Cell*. 2018. 33(4):634-648.e5.<sup>2</sup>National Cancer Institute, Cancer Stat Facts: Myeloma  
(<https://seer.cancer.gov/statfacts/html/mulmy.html>)



Source: Cerecor Inc.