

February 3, 2020



# Cerecor and Aevi Genomic Medicine Complete Merger

***-Cerecor Emerges as a Leading Biopharmaceutical Company in Rare Pediatric and Orphan Diseases***

***-Mike Cola Named Chief Executive Officer and Dr. Garry Neil Named Chief Medical Officer***

ROCKVILLE, Md., Feb. 03, 2020 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases, announced today it has completed the previously announced acquisition of Aevi Genomic Medicine (NASDAQ: GNMX) in an all-stock transaction valued at approximately \$15.6 million at close, plus contingent value rights (CVRs) for up to an additional \$6.5 million in subsequent payments based on clinical and/or regulatory milestones. Cerecor's pipeline now includes six clinical-stage assets, accelerating the Company's transformation into a research and development organization focused on developing new medicines for unmet needs in rare diseases, particularly for pediatric patients. The Company continues to explore strategic alternatives for its non-core neurological assets, including CERC-301, as well as its sole commercialized product, Millipred®.

Mike Cola, Chief Executive Officer, Cerecor, stated, *"Cerecor began this transformation roughly 15 months ago with the acquisition of the CERC-800s, which have the potential to be the first-ever approved treatments for Congenital Disorders of Glycosylation (CDGs). Following the more recent divestiture of the majority of the commercial pediatric portfolio and the acquisition of Aevi, today the Company is proud to advance a robust pipeline of six clinical-stage rare disease programs with the potential to be first-in-class medicines addressing high unmet needs of patients and families. Four of these programs are potentially Priority Review Voucher (PRV) eligible, with three already granted Rare Pediatric Disease Designation (RPDD) by the FDA. Cerecor is focused on achieving several critical inflection points throughout 2020, including initiation of pivotal studies for one or more CERC-800 program(s) and clinical proof-of-concept studies in patients with the recently integrated Aevi assets: CERC-002, CERC-006 and CERC-007. We believe this combination of assets present a unique opportunity to efficiently deliver high impact medicines by leveraging biomarker-driven approaches in clinical development"*.

## **Pipeline Assets Accelerate Company Transformation**

- **Commitment to Rare Pediatric and Orphan Diseases:** Cerecor continues its commitment to becoming an R&D-focused biopharmaceutical company with a robust pipeline of rare pediatric and orphan disease programs. This transaction expands the number of clinical programs in development at Cerecor while creating depth of focus in

rare pediatric and orphan diseases.

- **Pipeline Assets:** The emerging clinical-stage pipeline consists of six medicines with compelling biological rationale in orphan autoimmune, metabolic and oncology indications, with the potential for multiple product launches through 2023:
  - CERC-002 (formerly AEVI-002), a fully-human, anti-LIGHT monoclonal antibody for Pediatric Onset Crohn's Disease
  - CERC-006 (formerly AEVI-006), a potent, orally-available mTORC1/2 inhibitor for complex Lymphatic Malformations
  - CERC-007 (formerly AEVI-007), a fully-human, anti-IL-18 monoclonal antibody for auto-inflammatory diseases, including Adult Onset Still's Disease (AOSD) and Multiple Myeloma)
  - CERC-801, an ultra-pure, D-Galactose substrate replacement therapy for PGM1-CDG
  - CERC-802, an ultra-pure, D-Mannose substrate replacement therapy for MPI-CDG
  - CERC-803, an ultra-pure, L-Fucose substrate replacement therapy for SLC35C1-CDG

## Details of the Transaction

For details of the transaction please see the Investor Relations section of [Cerecor.com](http://www.cerecor.com).

## New Officers Appointed

Michael Cola has been appointed as the Chief Executive Officer and Dr. Garry Neil has been appointed as the Chief Medical Officer of Cerecor.

Mr. Cola brings a wealth of leadership experience in the biopharmaceutical industry. Prior to joining Cerecor, Mr. Cola served as President and CEO of Aevi Genomic Medicine since September 2013. Prior to joining Aevi Genomic Medicine, Mr. Cola served as President of Specialty Pharmaceuticals at Shire plc, a global specialty pharmaceutical company, from 2007 until April 2012. He joined Shire in 2005 as EVP of Global Therapeutic Business Units and Portfolio Management. Prior to joining Shire, he was with Safeguard Scientifics, Inc., a growth capital provider to life sciences and technology companies, where he served as President of the Life Sciences Group. While at Safeguard, Mr. Cola served as Chairman and CEO of Clariant, Inc., a cancer diagnostics company subsequently acquired by GE Healthcare, and as Chairman of Laureate Pharma, Inc., Prior to Safeguard Scientifics, Mr. Cola held senior positions in product development and commercialization at Astra Merck, a top 20 U.S. pharmaceutical company, and at Astra Zeneca, a global biopharmaceutical company. Mr. Cola received a B.A. in biology and physics from Ursinus College and an M.S. in biomedical science from Drexel University. He serves on the Board of Directors of Vanda Pharmaceuticals Inc., Sage Therapeutics and Phathom Pharmaceuticals, and currently serves as Chairman of the Board of Governors of the Boys & Girls Clubs of Philadelphia.

Prior to becoming the Chief Medical Officer at Cerecor, Dr. Garry Neil served as Chief Scientific Officer of Aevi Genomic Medicine since September 2013. Prior to joining Aevi

Genomic Medicine, Dr. Neil held a number of senior positions in the pharmaceutical industry, academia and venture capital. These include Corporate VP of Science & Technology at Johnson & Johnson, and Group President at Johnson & Johnson Pharmaceutical Research and Development, VP of R&D at Merck KGaA/EMD Pharmaceuticals, VP of Clinical Research at Astra Zeneca and Astra Merck. Dr. Neil holds a B.S. from the University of Saskatchewan and an M.D. from the University of Saskatchewan College of Medicine. He completed his postdoctoral clinical training in internal medicine and gastroenterology at the University of Toronto. Dr. Neil also completed a postdoctoral research fellowship at the Research Institute of Scripps Clinic. He is the Founding Chairman of the Pharmaceutical Industry R&D Consortium, TransCelerate Biopharmaceuticals Inc. He also serves on the Boards of Arena Pharmaceuticals, the Reagan Udall Foundation and the Center for Discovery and Innovation at Hackensack Meridian Health. He is past Chairman of the Pharmaceutical Research and Manufacturers Association (PhRMA) Science and Regulatory Executive Committee and the PhRMA Foundation Board. He is a past member of the Boards of GTx Pharmaceuticals, the Foundation for the National Institutes of Health (FNIH), and the Science Management Review Board of the NIH.

Additionally, Mr. Cola and Dr. Sol J. Barer will be joining the Board of Directors during the first quarter of 2020. Dr. Barer's long career as a senior pharmaceutical executive with leadership roles in various biopharmaceutical companies, coupled with his experience and knowledge of the global pharmaceutical industry and extensive scientific expertise will be a valuable addition to the Cerecor Board of Directors.

The independent directors of the Board approved, pursuant to NASDAQ Listing Rule 5635(c)(4), the grant of inducement equity awards in the form of stock options to Mr. Cola to purchase 1.2 million shares of common stock, to Dr. Neil to purchase 800,000 shares of common stock and to Dr. Jeffery Wilkins, our new Chief Development Officer, to purchase 375,000 shares of common stock. Each inducement option grant will vest over four years, with the first 25% of such option vesting on the first anniversary of the date of grant, and the remainder vesting in equal monthly installments, subject to the continued service of Mr. Cola, Dr. Neil, or Dr. Wilkins respectively, through the applicable vesting date.

Dr. Simon Pedder, Cerecor's Executive Chairman of the Board, added, "*We are extremely pleased to complete this acquisition. We welcome Mike and Garry to Cerecor's management team and Dr. Barer to our Board of Directors. The combined pipeline and leadership team create an exciting platform for the Company to solidify itself as a leader in rare pediatric and orphan drug development. The team is focused on executing and advancing the pipeline to near-term inflection points throughout 2020 that can set the stage for multiple drug approvals in the years to come, starting as soon as 2021.*"

### **About CERC-002**

CERC-002 (formerly AEVI-002) is an anti-LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for HVEM, a receptor expressed by T lymphocytes (part of the Tumor Necrosis Super Family 14)), fully human, monoclonal antibody being developed as a treatment for Pediatric Onset Crohn's Disease. CERC-002 is currently in a Phase I trial in adult Crohn's patients and has recently dosed the first patient, we anticipate initial data in the first half of 2020.

### **About CERC-006**

CERC-006 (formerly AEVI-006) is an mTORC1/2 inhibitor (a class of drugs that inhibit the mammalian target of rapamycin) being developed as a treatment for complex Lymphatic Malformations (LM). LM patients often have activating mutations along the PI3K/AKT/mTOR pathway; sirolimus, an mTORC1 inhibitor, has demonstrated clinical utility in LM. CERC-006 has the potential to improve upon both the safety and efficacy of mTOR inhibition in LM. Cerecor seeks to initiate a Phase 1b/2a proof-of-concept study of CERC-006 in LM patients by the end of 2020.

### **About CERC-007**

CERC-007 (formerly AEVI-007) is a fully human, anti-IL-18 monoclonal antibody with the potential to address multiple auto-inflammatory diseases, including Adult Onset Still's Disease (AOSD) and Multiple Myeloma (MM). IL-18 is a pro-inflammatory cytokine that stimulates the production of interferon gamma; patients with AOSD and MM show elevated serum levels of IL-18. Cerecor seeks to initiate two separate Phase 1b/2a proof-of-concept studies in AOSD and MM patients in the second half of 2020.

### **About CERC-800s**

CERC-801, CERC-802 and CERC-803 are monosaccharide substrate replacement therapies with known therapeutic utility for the treatment of Congenital Disorders of Glycosylation. 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. The FDA has granted RPDD and Orphan Drug Designation (ODD) to all three CERC-800 programs. CERC-801 and CERC-802 have completed phase 1 studies and the IND filing for CERC-803 is anticipated in the first half of 2020. The Company has an ongoing retrospective study, CDG FIRST, which seeks to collect natural history and treatment-related data for patients diagnosed with PGM1-CDG, MPI-CDG or SLC35C1-CDG who are either treated with or without D-galactose, D-mannose and L-fucose, respectively, as well as patients with other CDGs who are treated with one of the three monosaccharides. Cerecor seeks to initiate a pivotal study for one or more CERC-800 program(s) in 2020, with the first anticipated NDA filing in 2021.

### **About Cerecor**

Cerecor is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare pediatric and orphan diseases. The Company is advancing an emerging clinical-stage pipeline of innovative therapies. The Company's pediatric rare disease pipeline is led by CERC-801, CERC-802 and CERC-803 ("CERC-800 programs"), which are therapies for inborn errors of metabolism, specifically disorders known as Congenital Disorders of Glycosylation (CDGs). The FDA granted Rare Pediatric Disease Designation and Orphan Drug Designation ("ODD") to all three CERC-800 compounds, thus qualifying the Company to receive a Priority Review Voucher ("PRV") upon approval of a new drug application ("NDA"). The Company plans to leverage the 505(b)(2) NDA pathway for all three compounds to accelerate development and approval. The Company is also developing CERC-002, CERC-006 and CERC-007. CERC-007 is an anti-IL-18 monoclonal antibody being developed for autoimmune inflammatory diseases such as Adult Onset Still's Disease (AOSD) and Multiple Myeloma, with initial proof-of-concept in patients expected in 2021. CERC-006 is an mTORC1/2 inhibitor targeted towards complex Lymphatic

Malformations, also with initial proof-of-concept in patients expected in 2021. CERC-002 is an anti-LIGHT monoclonal antibody currently in a Phase 1 clinical trial; initial proof-of-concept data is expected in the first half of 2020 in Adult Crohn's Disease, an FDA requirement before proceeding into Pediatric Onset Crohn's. The Company is also developing one other preclinical pediatric orphan rare disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome.

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 Aevi's or 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 integration of the companies and their personnel; 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; strategic alternatives for the neurological assets and Millipred; 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: risks related to integration of the combined company; drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials; regulatory risks; reliance on and the need to attract, integrate and retain key personnel, including Mr. Cola and Dr. Neil; Cerecor's cash position and the need for it to raise additional capital; risks related to potential strategic alternatives for the Company's neurology assets and Millipred; and those other risks detailed in Aevi's and 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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