Cerecor to Acquire Aevi Genomic Medicine

-Expands Clinical-stage Pipeline, Further Positioning Cerecor as a Leader in Rare and Orphan Diseases
-Enhances Leadership Team with the Addition of Chief Executive Officer and Chief Medical Officer
-Strategic Alternatives Being Explored for Neurological Assets and Millipred®

ROCKVILLE, Md., Dec. 05, 2019 (GLOBE NEWSWIRE) -- Cerecor Inc. (NASDAQ: CERC), a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for orphan and rare diseases, as well as neurology announced today it has entered into a definitive merger agreement to acquire Aevi Genomic Medicine (NASDAQ: GNMX) in an all-stock transaction valued at approximately $16.1 million at closing, plus contingent value rights, or CVRs, for up to an additional $6.5 million in subsequent milestone payments on clinical or regulatory successes, or both. Additionally, the Company is exploring strategic alternatives for its neurological assets as well as its one commercialized product Millipred®.

“This deal is transformative for both organizations and solidifies Cerecor’s commitment to developing new medicines for rare and orphan diseases,” said Dr. Simon Pedder, Executive Chairman of the Board, Cerecor. “This acquisition expands our rare disease pipeline with the addition of three clinical-stage programs in areas of high unmet need. Additionally, the merger of Aevi into Cerecor will enhance our leadership team with the appointment of Mike Cola as Chief Executive Officer and Dr. Garry Neil as Chief Medical Officer upon closing.”

Deal Components

- The transaction is structured as a merger and is anticipated to be tax-deferred to the Aevi stockholders, with Cerecor retaining its public reporting and current NASDAQ listing status.
- Cerecor will acquire all outstanding shares of Aevi stock at an aggregate purchase price of $16.1 million less an amount by which Aevi’s net assets at closing are less than negative $1.3 million, but in no event will such adjustment be more than $500,000. The per share price will be based on the number of Aevi shares outstanding immediately prior to closing, which, including the shares of Aevi stock to be issued to Children’s Hospital of Philadelphia Foundation upon conversion of its outstanding secured promissory note and to AstraZeneca in connection with the exercise by Aevi of its license option for MEDI2338, is anticipated to result in an approximate per share value of $0.134 to Aevi stockholders, assuming the maximum net asset related adjustment.
- Cerecor will issue contingent value rights to former Aevi stockholders, which would entitle them to an additional $2 million in cash or stock (at Cerecor’s discretion) upon the enrollment of a patient in a Phase II study related to the AEVI-002, AEVI-006 or AEVI-007 within 24 months.
- The contingent value rights also entitle former Aevi stockholders to an additional $4.5 million in cash or stock (at Cerecor’s discretion) upon FDA approval of a New Drug Application (NDA) for AEVI-007 (MEDI2338) or AEVI-006 (OSI-027) within 60 months.
- Closing is targeted during the first quarter of 2020, subject to effectiveness of a Cerecor registration statement on Form S-4, Aevi shareholder approval and other standard closing conditions.

Benefits of the Transaction

- Commitment to Rare and Orphan Diseases: Cerecor continues its commitment to becoming an R&D-focused biopharmaceutical company with a robust pipeline of rare and orphan disease programs. This transaction expands the number of clinical programs in development at Cerecor while creating depth of focus in rare and orphan and pediatric diseases. To that end, the Company looks forward to continuing Aevi’s work with Children’s Hospital of Philadelphia in the field of rare and orphan diseases.

- Value creation through pipeline assets: The integration of Aevi’s pipeline programs should enhance the Cerecor pipeline and broaden an already rich set of near-term inflection points for Cerecor’s rare and orphan disease portfolio, which includes the CERC-800s. Aevi’s clinical-stage programs have the potential to benefit a variety of patient populations with significant unmet needs. Additionally, one or more of Aevi’s programs may be eligible for a Priority Review Voucher (PRV) granted by the Food and Drug Administration (FDA) associated with Rare Pediatric Disease (RPD) Designation. FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. Under this program, a sponsor who receives
an approval for a drug or biologic for a "rare pediatric disease" (RPD) may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.

- **AEVI-007** is a fully human anti-IL-18 monoclonal antibody with the potential to address multiple auto-inflammatory diseases, including Adult Onset Stills Disease (AOSD) and Multiple Myeloma (MM). IL-18 is a pro-inflammatory cytokine; patients with AOSD and MM show elevated levels of IL-18. Cerecor seeks to initiate a Phase 1b/2a proof-of-concept study of AEVI-007 in AOSD and MM patients in 2020.

- **AEVI-006** is an mTORC1/2 inhibitor (a class of drugs that inhibit the mammalian target of rapamycin) targeted towards Complex Lymphatic Malformations (LM). LM patients often have activating mutations along the PI3K/AKT/mTOR pathway and sirolimus is an mTORC1 inhibitor that has demonstrated clinical utility in LM. AEVI-006 has the potential to improve on both the safety and efficacy of mTOR inhibition in LM. Cerecor seeks to initiate a Phase 1b/2a proof-of-concept study of AEVI-006 in LM patients in 2020.

- **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 Crohn’s Disease. AEVI-002 is currently in a Phase I study in adult Crohn’s patients and has recently dosed the first patient. We anticipate initial data in the first half of 2020.

- **Aligns with Cerecor’s transformation and innovation strategy:** Cerecor’s pipeline strategy is focused on developing new medicines for rare and orphan diseases. Aevi’s pipeline programs complement Cerecor’s existing pediatric rare disease pipeline 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. The FDA has granted RPD Designation and Orphan Drug Designation (“ODD”) to all three CERC-800 compounds, thus qualifying the Company to receive a PRV upon approval of an NDA.

- **Organizational fit:** Upon closing of the merger, it is expected that Mike Cola, current Chief Executive Officer of Aevi, will become Chief Executive Officer of Cerecor and Dr. Garry Neil, current Chief Scientific Officer of Aevi, will become Chief Medical Officer of Cerecor. Both of these individuals bring a wealth of clinical development and commercialization experience in the biopharmaceutical industry and should complement and enhance the executive leadership team at Cerecor.

Mike Cola, Chief Executive Officer of Aevi, stated, “We at Aevi Genomics are extremely excited about joining the Cerecor organization. The combined pipeline of both organizations is an immediate transformation of Cerecor into a leading biopharmaceutical company focused in the Rare and Orphan Disease space. The pipeline of six near-term assets are focused in areas of significant unmet need where there are no or few approved therapies. While there is a lot of work to do in our ongoing clinical programs, I feel confident that the combined team will be able to submit numerous NDAs and gain FDA approvals over the next several years to bring new therapies to patients and families in need.”

**About the Transaction**

Wedbush PacGrow is acting as the exclusive strategic advisor to Aevi and Pepper Hamilton LLP is serving as its legal counsel. Wyrick Robbins Yates & Ponton LLP is serving as Cerecor’s legal counsel.

**Strategic Optionality for Two Neurological Assets and Millipred® (oral prednisolone)**

The addition of three clinical programs in the rare disease space solidifies Cerecor’s strategic focus as a biopharmaceutical company focused on the treatment of rare and orphan diseases. The Company plans to concentrate resources toward advancing those assets to critical clinical and regulatory milestones. As a result, and based on multiple inbound expressions of interest, the Company is evaluating strategic options for its neurological assets, CERC-301, a clinical-stage program being evaluated in diseases characterized by orthostatic hypotension, CERC-406, a next-generation, CNS-penetrant COMT inhibitor for Parkinson’s disease, and for Millipred® (5mg oral prednisolone), Cerecor’s sole remaining commercial asset.

**About Aevi Genomic Medicine**

Aevi Genomic Medicine, Inc. is dedicated to unlocking the potential of genomic medicine to translate genetic discoveries into novel therapies. Driven by a commitment to patients with pediatric onset life-altering diseases, Aevi’s research and development efforts include working with the Center for Applied Genomics (CAG) at Children’s Hospital of Philadelphia to leverage novel genetic discoveries to progress its genomic medicine strategy.

**About CERC-800’s**
CERC-801, CERC-802 and CERC-803 represent monosaccharide substrate replacement therapies with established 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.

About CERC-301

CERC-301 is an orally available, NR2B-specific, NMDA receptor antagonist being developed for the treatment of symptomatic orthostatic hypotension (OH), specifically being investigated in neurogenic Orthostatic Hypotension, (nOH) Diabetic Orthostatic Hypotension (DOH) and Intradialytic Hypotension (IDH) associated with End Stage Renal Disease (ESRD) and hemodialysis.

About CERC-406

CERC-406 is a small molecule, selective, catechol-O-methyltransferase (or COMT) inhibitor being developed as an oral neuro-selective adjunctive medication to levodopa / carbidopa in patients experiencing the "off-periods" of symptom management with Parkinson’s Disease.

About Millipred®

Millipred is an oral prednisolone that is commercially available and is being actively marketed in the United States. Millipred is indicated across a wide variety of inflammatory conditions: Endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, edematous states, gastrointestinal diseases, nervous system, and certain miscellaneous indications. (Please see Full Package Insert at www.cerecor.com)

- Prednisolone is rapidly absorbed following an oral dose
- Peak effects following oral administration occur within 1—2 hours.
- Rapid onset of action with intermediate duration of action
- Prednisolone is preferred to prednisone in significant hepatic disease because prednisolone does not require hepatic activation
- No dosage adjustments are needed in renally impaired

About Cerecor

Cerecor is a biopharmaceutical company focused on becoming a leader in development and commercialization of treatments for rare and orphan diseases, as well as neurological conditions. The Company is building a robust 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. 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 PRV may be sold or transferred an unlimited number of times. 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 one other preclinical pediatric orphan rare disease compound, CERC-913, for the treatment of mitochondrial DNA Depletion Syndrome. The Company’s neurology pipeline is led by CERC-301, a Glutamate NR2B selective, NMDA Receptor antagonist, which Cerecor is currently exploring as a novel treatment for orthostatic hypotension. The Company is also developing CERC-406, a CNS-targeted COMT inhibitor for Parkinson’s Disease. The Company also has one marketed product, Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions and indications. 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 Aevi’s or 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 timing of closing of the merger with Aevi; 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: risks that the merger might not close as soon as expected or at all; 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. Neill; 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.

Important Information and Where to Find It

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities of Aevi or Cerecor or the solicitation of any vote or approval. In connection with the proposed transaction, Cerecor will file with the SEC a Registration Statement on Form S-4 containing a proxy statement/prospectus. The proxy statement/prospectus will contain important information about Aevi, Cerecor, the transaction and related matters. Aevi will mail or otherwise deliver the proxy statement/prospectus to its stockholders when it becomes available. Investors and security holders of Aevi and Cerecor are urged to read carefully the proxy statement/prospectus relating to the merger (including any amendments or supplements thereto) in its entirety when it is available, because it will contain important information about the proposed transaction.

Investors and security holders of Aevi and Cerecor will be able to obtain free copies of the proxy statement/prospectus for the proposed merger (when it is available) by contacting Aevi, Attn: Mike McInaw, michael.mcinaw@aevigenomics.com. Investors and security holders of Cerecor will be able to obtain free copies of the proxy statement/prospectus for the merger by contacting Cerecor, Attn: James Harrell, jharrell@cerecor.com.

Aevi and Cerecor, and their respective directors and certain of their executive officers, may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the agreement between Aevi and Cerecor. Information regarding Aevi’s directors and executive officers is contained in Aevi’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 29, 2019, and will also be available in the proxy statement/prospectus that will be filed by Cerecor with the SEC in connection with the proposed transaction. Information regarding Cerecor’s directors and executive officers is contained in Cerecor’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 18, 2019, and will also be available in the proxy statement/prospectus that will be filed by Cerecor with the SEC in connection with the proposed transaction.

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