Achaogen Provides Update on Corporate Progress and Key Preliminary Fourth Quarter 2018 Results

February 14, 2019

-- Company provides update on ZEMDRI® commercialization and launch --

-- Data from both the EPIC and CARE Phase 3 clinical studies of plazomicin are expected in peer-reviewed publication --

SOUTH SAN FRANCISCO, Calif., Feb. 14, 2019 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ: AKAO), a biopharmaceutical company discovering, developing and commercializing innovative antibacterial agents to address multi-drug resistant (MDR) gram-negative infections, today shared certain key preliminary unaudited results for the fourth quarter ended December 31, 2018, and provided an update on its commercial and corporate activities.

"As our previously announced review of strategic alternatives continues, I am pleased with the steady progress of the ZEMDRI commercial launch and especially the commitment of the entire company to bringing this important medicine to the infectious disease community," said Blake Wise, Achaogen's Chief Executive Officer. "Our leading sales indicators continue to trend in a positive direction, we expect near term publication of our Phase 3 trials and we remain hopeful that additional corporate initiatives, such as the dispute resolution process underway with the FDA to address a potential bloodstream infection indication for plazomicin, may drive further shareholder value."

Recent Highlights and Upcoming Milestones

- **ZEMDRI Launch Update:** Overall, we believe that positive progress is being made with the launch of ZEMDRI.

  • **Product Use:** The proportion of ZEMDRI outpatient sales continues to increase and accounts for 75% of sales to date. We expect to see continued progress in outpatient treatment given the advantages of ZEMDRI's once-daily 30 minute infusion. The Company continues to establish contracts with physician-owned infusion centers, 200 of which have requested or are under contract for ZEMDRI.

  • **Formulary Approvals:** The Company currently has 153 hospital formulary approvals for ZEMDRI, including approval at six major hospital systems. The formulary approval rate is 98% to date. Given recent formulary approvals and the receipt of a permanent C-code in January 2019, we believe that both hospitals and hospital outpatient departments have improved access to, and reimbursement for, ZEMDRI.

  • **Testing:** The Thermo Scientific QMS Plazomicin Immunoassay became commercially available in the fourth quarter of 2018, enabling assay validation in hospital labs. Achaogen expects this assay to also be available through reference labs in the second quarter of 2019. New accounts also continue to adopt ZEMDRI antibiotic susceptibility testing (AST) in their microbiology laboratories to support appropriate patient selection.

- **BSI Dispute Resolution:** In December 2018, Achaogen filed a Formal Dispute Resolution Request with the FDA regarding the indication for plazomicin for the treatment of bloodstream infections (BSI), for which the FDA issued a Complete Response Letter in June 2018. The Company believes that the data submitted in the New Drug Application for plazomicin provides substantial evidence of efficacy in treating BSI and believes that plazomicin should be approved for the proposed BSI indication. As part of this process, the Company has received questions from, and submitted responses to, the FDA. The Company is now awaiting a first-round response from the FDA.

- **Peer-Reviewed Publication of Phase 3 Data**: A prestigious medical journal has accepted for publication the data from both the EPIC and CARE Phase 3 clinical studies of plazomicin. The Company expects these publications to become available shortly.

- **European Marketing Authorization Application (MAA)**: The Company filed an MAA for plazomicin with the European Medicines Agency (EMA) in the fourth quarter of 2018. The Company anticipates receiving the Day 120 questions by the end of the first quarter of 2019, after which it will continue to advance the regulatory process with the rapporteurs and the EMA.

- **C-Scape:** The Company recently completed *in vitro* and *in vivo* experiments with a revised drug product and, based on these results, is starting a Phase 1 clinical pharmacology study with the revised drug product in 2019. The Company believes that these data may also potentially support extended intellectual property protection of C-Scape beyond the eight years of regulatory exclusivity granted by Qualified Infectious Disease Product (QIDP) status.

Strategic Review

- **Strategic Review Continues**: In November 2018, the Company announced the beginning of a review of strategic alternatives to maximize stockholder value, including but not limited to the potential sale or merger of the Company or its assets. The strategic review continues alongside the Company's continued focus on the commercialization of ZEMDRI and other corporate initiatives.

Key Preliminary Fourth Quarter 2018 Financial Results (Unaudited)

Cash Position: Achaogen expects to report that it had approximately $31.0 million in unrestricted cash and cash equivalents as of December 31, 2018. In addition, it expects to report $25.5 million of restricted cash, representing total expected cash and cash equivalents of $56.5 million as of December 31, 2018.

Net Product Sales: Achaogen expects to report net product sales of ZEMDRI of approximately $450,000 to $500,000 for the three months ended December 31, 2018. This estimate does not include contract revenues, which will be included in total revenues.

The Company has not completed the preparation of its financial statements for the quarter ended December 31, 2018, and additional details with respect to fourth quarter 2018 results of operations are not yet available. The Company plans to release financial results for the fourth quarter and full year 2018 through a press release in March 2019.

While reviewing potential strategic alternatives, the Company is focused on making progress on its key priorities: ZEMDRI commercialization, EMA approval for plazomicin and C-Scape development.

About Achaogen
Achaogen is a biopharmaceutical company passionately committed to the discovery, development, and commercialization of innovative antibacterial treatments for MDR gram-negative infections. Achaogen's first commercial product is ZEMDRI, for the treatment of adults with complicated urinary tract infections, including pyelonephritis. The Achaogen ZEMDRI program was funded in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA). The Company is currently developing C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination, which is also supported by BARDA. C-Scape is investigational, has not been determined to be safe or efficacious, and has not been approved for commercialization.

Forward-Looking Statements
The 2018 preliminary cash and net product sales contained in this news release are subject to finalization in connection with the preparation of the Company's Annual Report on Form 10-K for the year ended December 31, 2018. This press release contains forward-looking statements. All statements other than statements of historical facts contained herein are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the Company's fourth quarter 2018 financial results, the timing and release of financial results for the fourth quarter and full year 2018, the potential uses and advantages of ZEMDRI (plazomicin), launch metrics for ZEMDRI, the approval of plazomicin by the EMA, the outcome of Achaogen's strategic review, the outcome of Achaogen's dispute resolution process at the FDA, Achaogen's strategic and commercial objectives and the Achaogen pipeline of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause Achaogen's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the risks and uncertainties that the strategic review may not be successful or may lead to unexpected outcomes, the risks and uncertainties of commercialization and gaining market acceptance for ZEMDRI, uncertainties inherent in the development process, the risks and uncertainties of the regulatory approval process with the EMA and the dispute resolution process with the FDA, the risk when bacteria will evolve resistance to ZEMDRI, Achaogen's reliance on third-party contract manufacturing organizations to manufacture and supply ZEMDRI, its product candidates and certain raw materials used in the production thereof and the risk that Achaogen's proprietary rights may be insufficient to protect ZEMDRI, its technologies and product candidates. Further, estimates of the Company's net product sales for the quarter ended December 31, 2018 and cash and cash equivalents as of December 31, 2018 are preliminary and unaudited; actual amounts that are reported will be subject to the Company's financial closing procedures and any final adjustments that may be made prior to the time that financial results for the fourth quarter of 2018 are finalized and filed with the Securities and Exchange Commission (SEC). For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Achaogen business in general, see Achaogen's current and future reports filed with the SEC, including its Annual Report on Form 10-K filed on February 27, 2018, and its Quarterly Report on Form 10-Q filed on November 8, 2018. Achaogen does not plan to publicly update or revise any forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances, or otherwise.

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Source: Achaogen, Inc.