ACHAOGEN

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Achaogen Completes Patient Enrollment in Phase 3 EPIC Clinical Trial of Plazomicin

Top-Line Data in Phase 3 EPIC and CARE Studies Expected Early in First Quarter of 2017; Planning NDA Submission for Second Half of 2017

SOUTH SAN FRANCISCO, Calif., Sept. 01, 2016 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a clinical-stage biopharmaceutical company developing novel antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today announced that it has completed patient enrollment ahead of schedule in its Phase 3 EPIC registration clinical trial of plazomicin. Additionally, the Company has closed enrollment in the Phase 3 CARE trial of plazomicin and expects to report top-line results from both the EPIC and CARE clinical trials early in the first quarter of 2017. Achaogen is developing plazomicin to treat serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (CRE).

"We are extremely grateful to the patients, investigators and clinical trial sites that participated in the EPIC trial. Their extraordinary teamwork enabled us to quickly enroll the EPIC trial in less than eight months, significantly faster than our original projections. We look forward to announcing top-line data early in the first quarter next year," said Kenneth Hillan, M.B., Ch.B., Achaogen's Chief Executive Officer. "With the rapid completion of the EPIC trial, we closed enrollment in the CARE trial several months earlier than anticipated and we are one step closer to our goal of submitting the plazomicin NDA in the second half of 2017 and, if approved, making plazomicin available as an important option for treating patients with CRE infections."

About the Phase 3 EPIC Clinical Trial
EPIC (**E**valuating **p**lazomicin **i**n **c**UTI) is a multi-national, randomized, controlled, double-blind clinical trial in patients with complicated urinary tract infections (cUTI), including acute pyelonephritis (AP), which is expected to create a substantial opportunity for plazomicin to address the unmet medical need arising from multi-drug resistant (MDR) infections. EPIC is evaluating the efficacy and safety of plazomicin compared to meropenem and 609 patients were randomized to receive either plazomicin or meropenem intravenously. The primary objective of the EPIC trial is to demonstrate the non-inferiority, with a 15% non-inferiority margin as agreed by FDA, of plazomicin compared to meropenem based on the difference in composite microbiological eradication and clinical cure rate in the microbiological modified intent-to-treat (mMITT) population at both the Day 5 and test-of-cure visits. The Company expects the EPIC trial to serve as a single registration trial and support a New Drug Application (NDA) submission in the second half of 2017.

About the Phase 3 CARE Clinical Trial
CARE (**C**ombating **A**ntibiotic **R**esistant **E**nterobacteriaceae) is a resistant pathogen-specific trial that describes the efficacy and safety of plazomicin in patients with infections due to CRE. Due to the rapid completion of enrollment of the EPIC trial, the Company closed enrollment in the CARE trial several months earlier than anticipated with a total of 69 patients enrolled. CARE contains a randomized, open-label cohort (Cohort 1; 39 patients) that compares the efficacy and safety of plazomicin with colistin in the treatment of patients with bloodstream infections (BSI) or hospital-acquired pneumonia (HABP, VABP) due to CRE. An additional single-arm cohort (Cohort 2; 30 patients) enrolled patients with BSI, HABP, VABP, cUTI or AP due to CRE, and who were not eligible for enrollment in Cohort 1, to be treated with plazomicin-based therapy. The Company plans to submit the Phase 3 CARE trial results as supportive data with the plazomicin NDA, which is based on the Phase 3 EPIC trial, and to submit the results to peer-reviewed journals and for presentation at medical meetings. The CARE trial is primarily a descriptive study (no formal hypothesis testing will be performed); the Company believes the trial will provide important and meaningful data regarding the efficacy, safety, microbiology, and dosing, to better inform physician use of plazomicin in the potential treatment of patients with CRE infections.

About Achaogen
Achaogen is a clinical-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterials to treat MDR gram-negative infections. Achaogen is developing plazomicin, Achaogen's lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. Achaogen's plazomicin program is funded in part with Federal funds from the Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, under Contract No. HHSO100201000046C. Plazomicin is the first clinical candidate from Achaogen's gram-negative antibiotic discovery engine, and Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections. For more information, please visit www.achaogen.com.

Forward-Looking Statements

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, Achaogen's expectations regarding (i) whether the Phase 3 EPIC trial will serve as a single registration clinical trial supporting an NDA for plazomicin, (ii) the timing for completion of Achaogen's Phase 3 trials and submission of an NDA to the FDA, (iii) the potential for plazomicin to treat serious bacterial infections due to MDR Enterobacteriaceae and patients with CRE infections; (iv) whether the Phase 3 EPIC trial will create a substantial opportunity for plazomicin to address the unmet medical need arising from MDR infections; (v) the Company's plans to submit the Phase 3 CARE trial results as supportive data with the plazomicin NDA based on the Phase 3 EPIC trial and to submit the Phase 3 CARE trial results to peer-reviewed journals and for presentation at medical meetings; and (vi) whether the Phase 3 CARE trial will provide important and meaningful data regarding the safety, microbiology, and dosing, to better inform physician use of plazomicin in the potential treatment of patients with CRE infections. 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 uncertainties inherent in the preclinical and clinical development process; specific risks related to the ongoing Phase 3 EPIC trial and Phase 3 CARE trial, including the lack of a prior clinical trial in patients with CRE infections; the risk of failure to successfully validate, develop and obtain regulatory clearance or approval for the in vitro diagnostic (IVD) assay for plazomicin; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of commercialization and gaining market acceptance; the risk that bacteria may evolve resistance to plazomicin; risks and uncertainties as to Achaogen's ability to raise additional capital to support the development of plazomicin and its other programs; uncertainties regarding the availability of adequate third-party coverage and reimbursement for newly approved products; Achaogen's reliance on third parties to conduct certain preclinical studies and all of its clinical trials; Achaogen's reliance on third-party contract manufacturing organizations to manufacture and supply its product candidates and certain raw materials used in the production thereof; Achaogen's dependence on its President and Chief Executive Officer; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that BARDA could terminate Achaogen's contract for the funding of the plazomicin development program; risk of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Achaogen's patents or proprietary rights; and the risk that Achaogen's proprietary rights may be insufficient to protect its technologies and product candidates. 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 Achaogen's business in general, see Achaogen's current and future reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016. 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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