ACHAOGEN

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Achaogen Announces FDA Advisory Committee Voted Unanimously in Favor of Plazomicin for Treatment of Adults with Complicated Urinary Tract Infections

SOUTH SAN FRANCISCO, Calif., May 02, 2018 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a late-stage biopharmaceutical company developing innovative antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today announced that the U.S. Food and Drug Administration's (FDA) Antimicrobial Drugs Advisory Committee voted on the two points for Advisory Committee consideration as follows:

1. Has the applicant provided substantial evidence of the safety and effectiveness of plazomicin for the treatment of complicated urinary tract infections?

Result: (15-0-0) There were 15 yes votes and zero no votes. No members of the panel abstained.

2. Has the applicant provided substantial evidence of the safety and effectiveness of plazomicin for the treatment of bloodstream infections in patients with limited or no treatment options?

Result: (4-11-0) There were four yes votes and 11 no votes. No members of the panel abstained.

There were 16 panel members at the meeting, one of whom departed prior to the vote and was therefore not present for the voting.

"We are encouraged by the Committee's unanimous vote in favor of plazomicin for complicated urinary tract infections (cUTI). The discussion underscored the real-world challenges that healthcare providers face every day given limited or inadequate treatment options for certain pathogens," said Blake Wise, Achaogen's Chief Executive Officer. "Regarding bloodstream infections, the Limited-Population Antibacterial Drug pathway, or LPAD, is a novel approach that enables the FDA to consider the benefits and risks for the sickest patients who have few or no available treatment options, and to approve antibiotics like plazomicin that we believe, have the potential to address these limited patient populations."

The FDA is not bound by the Committee's votes but takes its input into consideration when reviewing marketing applications. Plazomicin has a Prescription Drug User Fee Act (PDUFA) date of June 25, 2018. If the FDA approves plazomicin by this target action date, Achaogen expects to launch plazomicin in the U.S. soon thereafter.

About Plazomicin and Multi-Drug Resistant (MDR) Gram-Negative Infections
Plazomicin is an aminoglycoside that was developed to treat serious bacterial infections due to multidrug resistant gram-negative bacteria including carbapenem-resistant Enterobacteriaceae (CRE), and has been evaluated in two Phase 3 clinical trials, EPIC and CARE. MDR gram-negative bacteria are a type of bacteria with resistance to multiple antibiotics. They can cause bacterial infections that pose a serious threat for hospitalized patients. The problem is extensive and growing; the Centers for Disease Control and Prevention (CDC) characterized CRE as "nightmare bacteria" and an immediate public health threat that requires "urgent and aggressive action". Patients with MDR infections often have limited or inadequate therapeutic options leading to high rates of mortality.

About Achaogen
Achaogen is a late-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of innovative antibacterial treatments for MDR gram-negative infections. Achaogen is developing plazomicin, its lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. The Food and Drug Administration has granted plazomicin Breakthrough Therapy designation for the treatment of bloodstream infections caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options. Achaogen's plazomicin program has been funded in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, under Contract No. HHSO100201000046C. The Company's second product candidate C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination, is funded in part with Federal funds from BARDA. Achaogen has other programs in early and late preclinical stages of development focused on MDR gram-negative infections and additional disease areas. All product candidates, including plazomicin, are investigational and have not been approved for commercialization. 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 potential regulatory approval of plazomicin and other product candidates, Achaogen's plan to launch plazomicin soon after receiving FDA approval and Achaogen's 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 uncertainties inherent in the preclinical and clinical development process; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of product sales and effectiveness; Achaogen's reliance on third-party contract manufacturing organizations for manufacture and supply, including sources of certain raw materials; 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 Annual Report on Form 10-K filed on February 27, 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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