ACHAOGEN

January 2, 2018

# Achaogen Announces FDA Acceptance of New Drug Application with Priority Review for Plazomicin for Treatment of Complicated Urinary Tract Infections and Bloodstream Infections

*-- Investigational drug has potential to treat certain MDR gram-negative pathogens, including carbapenem-resistant Enterobacteriaceae (CRE) --*

*-- FDA sets action date of June 25, 2018 --*

SOUTH SAN FRANCISCO, Calif., Jan. 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 (FDA) has accepted for review the Company's New Drug Application (NDA) for plazomicin for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, and bloodstream infections (BSI) due to certain Enterobacteriaceae in patients who have limited or no alternative treatment options. FDA has granted the NDA Priority Review and set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 25, 2018. Achaogen also intends to submit an application for marketing authorization in the European Union (EU) in 2018.

"The number of confirmed cases of CRE annually in the U.S. is at least 70,000, and is projected to double by 2022," said Blake Wise, Achaogen's Chief Executive Officer. "We are excited about plazomicin's potential to address certain multi-drug resistant gram-negative infections and feel that plazomicin would be a valuable new treatment option for patients with serious bacterial infections, including those due to CRE and ESBL-producing Enterobacteriaceae."

In its acceptance letter, the FDA has stated that it is currently planning to hold an advisory committee meeting to discuss this application. The NDA is supported by data from both the EPIC and CARE clinical trials which evaluated the safety and efficacy of plazomicin in patients with serious infections caused by gram-negative pathogens, including extended-spectrum beta-lactamase (ESBL) producing and carbapenem-resistant Enterobacteriaceae (CRE). The FDA granted Breakthrough Therapy designation for plazomicin for the treatment of bloodstream infections (BSI) caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options. Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs that target serious or life-threatening conditions. Plazomicin has also received Qualified Infectious Disease Product (QIDP) designation from the FDA which provides incentives for the development of new antibiotics, including priority review and an additional five years of market exclusivity.

**About FDA Priority Review Designation**
A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA goal for reviewing a drug with Priority Review status is six months from the time the application is filed by the FDA.

**About Plazomicin**
Plazomicin was developed to treat serious bacterial infections due to MDR Enterobacteriaceae, including extended-spectrum beta-lactamase (ESBL) producing and carbapenem-resistant Enterobacteriaceae (CRE), and has been evaluated in two Phase 3 clinical trials, EPIC and CARE.

**About Multi-Drug Resistant (MDR) Gram-Negative Infections**
Multidrug resistant gram-negative bacteria, including carbapenem-resistant Enterobacteriaceae (CRE), are gram-negative bacteria that are resistant to multiple antibiotics and 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". The CDC characterized ESBL-producing bacteria as a serious threat to public health. 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. Achaogen's plazomicin program has been 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. The Company's second product candidate is C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination. Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections and additional disease areas. All product candidates, including plazomicin, are investigational only 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 and label of plazomicin, Achaogen's plans regarding an application for marketing authorization in the European Union, plazomicin's potential to address certain MDR infections, plazomicin's potential to treat serious bacterial infections, including those due to CRE and ESBL-producing Enterobacteriaceae 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 uncertainties of having an NDA accepted by the FDA, the risks and uncertainties of the regulatory approval process; the risks and uncertainties of commercialization and gaining market acceptance; the risk when bacteria will evolve resistance to plazomicin or C-Scape; 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; 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 March 14, 2017 and its Quarterly Report on Form 10-Q filed on November 8, 2017. 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.

Source: Achaogen, Inc. (NASDAQ:AKAO)

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