ACHAOGEN

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Plazomicin Granted FDA Breakthrough Therapy Designation

Breakthrough Therapy designation supports the potential of plazomicin as a substantial improvement over existing therapies

SOUTH SAN FRANCISCO, Calif., May 23, 2017 (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) granted Breakthrough Therapy designation for plazomicin, Achaogen's lead product candidate being developed for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (CRE).

The Phase 3 CARE trial data provided clinical evidence to support the 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.

The Company is focused on developing plazomicin as a treatment option for patients with certain severe bacterial infections, and it intends to include the CARE trial data, along with data from the EPIC trial, in an NDA submission in the second half of 2017. In 2012, the FDA granted Fast Track designation for the development and regulatory review of plazomicin to treat serious and life-threatening CRE infections. In 2014, plazomicin received Qualified Infectious Disease Product (QIDP) designation from FDA for both the cUTI and BSI indications. QIDP designation provides certain incentives for the development of new antibiotics, including automatic priority review and an additional five years of market exclusivity.

About Breakthrough Therapy Designation
Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs that target serious or life-threatening conditions. A Breakthrough Therapy drug must show preliminary clinical evidence of a substantial improvement on a clinically significant endpoint over available therapies. The designation includes all of the Fast Track program features, as well as more intensive FDA guidance and discussion, including interactions with FDA across review divisions.

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, Achaogen's lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. FDA has granted plazomicin Breakthrough Therapy designation for the treatment of bloodstream infections (BSI) caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options. Achaogen's plazomicin program is 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. 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. All product candidates 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 of plazomicin, Achaogen's commercial objectives 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 risk the clinical development program does not continue to meet the criteria for Breakthrough Therapy designation and the designation is rescinded, the uncertainties inherent in the preclinical and clinical development process; 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; 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 for the fiscal year ended December 31, 2016, filed on March 14, 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.

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