Achaogen Announces FDA Clearance and Launch of the Thermo Scientific QMS Plazomicin Immunoassay

--- Thermo Fisher Scientific and Achaogen jointly develop new assay to enable Therapeutic Drug Management ---

SOUTH SAN FRANCISCO, Calif., Dec. 10, 2018 (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 announced that the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) has provided clearance for the Thermo Scientific QMS Plazomicin Immunoassay that provides a quantitative measure of plazomicin in human plasma using automated clinical chemistry analyzers. Results of the assay will be used to assist in the management of patients receiving plazomicin therapy.

Plazomicin, marketed as ZEMDRI™ in the United States, was approved by the U.S. Food and Drug Administration for the treatment of adults with complicated urinary tract infections, including pyelonephritis, due to certain Enterobacteriaceae.

“The QMS Plazomicin Immunoassay will enable therapeutic drug management (TDM) which is critical to support the use of ZEMDRI in a subset of the more than one million annual cases of multi-drug resistant or recurrent complicated urinary tract infections in the United States,” said Janet Dorling, Achaogen’s Chief Commercial Officer. “This is an important milestone and we are excited about the commercialization of the QMS Plazomicin immunoassay.”

Thermo Fisher Scientific and Achaogen jointly developed the QMS Plazomicin immunoassay. Both companies entered into a collaboration to develop an assay that would help healthcare professionals make important dosing determinations regarding the use of ZEMDRI for appropriate patients.

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, due to certain Enterobacteriaceae. 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. For more information, visit the Achaogen website at 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, the potential uses and advantages of ZEMDRI (plazomicin), 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 of commercialization and gaining market acceptance, uncertainties inherent in the development process, the risks and uncertainties of the regulatory approval process and the risk when bacteria will evolve resistance to ZEMDRI. 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 Securities and Exchange Commission, 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.

Source: Achaogen, Inc

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