ACHAOGEN

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Achaogen Announces Upgraded Status for Plazomicin Fill Manufacturer

-- McPherson, Kansas facility compliance status amended to Voluntary Action Indicated (VAI) --

-- VAI status provides a clear regulatory path for potential approval of plazomicin out of McPherson facility --

SOUTH SAN FRANCISCO, Calif., Jan. 30, 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 Food and Drug Administration (FDA) has classified the outcome of its fourth quarter 2017 reinspection of Pfizer's McPherson facility as Voluntary Action Indicated (VAI). The Company's New Drug Application (NDA) for plazomicin is currently under regulatory review, and the change to VAI status provides a clear regulatory path for approval for plazomicin out of the McPherson facility based on plazomicin's PDUFA date of June 25, 2018.

"The upgraded VAI designation received by Pfizer's McPherson facility is a positive outcome," said Blake Wise, Achaogen's Chief Executive Officer. "Our PDUFA date is five months away and, with additional clarity around our manufacturing efforts, we look forward to the potential marketing approval and launch of plazomicin."

The Company's NDA for plazomicin is 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. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 25, 2018.

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 (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 is C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination that is funded in part with federal funds from BARDA. 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 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 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; 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 for the quarter ended September 30, 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.

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