Achaogen Submits Response to ASPR/BARDA Request for Information (RFI) for Antimicrobial Resistance Project BioShield

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-- Plazomicin may be well-suited to play a critical role in biodefense preparedness --

SOUTH SAN FRANCISCO, Calif., Feb. 14, 2019 (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 it has responded to a Request for Information (RFI) regarding antibacterial products with the potential to treat resistant biothreat pathogens. The RFI was solicited by the Assistant Secretary for Preparedness and Response (ASPR) / the Biomedical Advanced Research and Development Authority (BARDA) under Project BioShield.

The RFI specifically requested information on availabilities and capabilities for procuring, stockpiling and investing in the ongoing development of antibiotic products for commercial use for treatment of multiple biodefense indications, including pneumonic plague and tularemia, for which plazomicin has demonstrated preclinical efficacy.

"We have continued to look for ways to expand our long and collaborative partnership with BARDA," said Blake Wise, Achaogen's Chief Executive Officer. "Project BioShield's mission of accelerating public health preparedness is profoundly important. We believe that plazomicin is well-suited to playing a critical role in biodefense preparedness and we are hopeful that industry responses to this RFI will encourage BARDA to progress to a Request for Proposal (RFP)."

Plazomicin, marketed as ZEMDRI® in the United States, was approved by the U.S. Food and Drug Administration (FDA) in June 2018 for the treatment of adults with complicated urinary tract infections, including pyelonephritis, due to certain Enterobacteriaceae. Plazomicin was developed through FDA approval with support from BARDA which provided $124.4 million in research and development funding over the lifetime of the program, starting in 2010.

Plazomicin is an aminoglycoside antibiotic designed to overcome the most clinically relevant mechanisms that inactivate older members of the class, such as gentamicin. Gentamicin is a mainstay of therapy for the treatment of threat pathogens such as *Yersinia pestis* (e.g. pneumonic plague) and *Franciscella tularensis* (e.g. pneumonic tularemia). Along with anthrax, these pathogens are considered "Category A" threats by the Centers for Disease Control and Prevention, representing the highest level threat due to ease of dissemination and transmission, and high associated mortality.

There is an increasing risk of having to confront resistant outbreaks of *Y. pestis* and *F. tularensis* as transmissible resistance in community and hospital pathogens increases. "Our appropriate focus on stewardship and targeted delivery of the newest drugs to address only the most resistant pathogens has created a dynamic that could severely hinder response time, by months or even years, if there is a sudden outbreak of a resistant form of a disease such as pneumonic plague," said Dr. Ryan Cirz, Achaogen's Vice President of Research. "A public-private partnership to better prepare for such an event would be an exciting development."

About the Antibiotic Resistance Project BioShield
Project BioShield is a comprehensive effort involving the U.S. Department of Health and Human Services (HHS), its component agencies, and other partner federal agencies to speed the research, development, acquisition and availability of medical countermeasures, such as antibiotics, to improve the government's preparedness for and ability to counter various threats to public health. Federal agencies use Requests for Information (RFI) as a form of market research. During the RFI process, component agencies, such as ASPR/BARDA, solicit information from stakeholders regarding capabilities to address a threat. Depending on the results of the RFI process, a Request for Proposals (RFP) may be put forth to solicit proposals from stakeholders to specifically address the threat. If the agency accepts the proposal, the stakeholder enters into a contract with the government. Historically, Project BioShield contracts include one or more of the following: government procurement of product for countermeasures; support of development activities to gain approval for use and/or expansion of use in additional populations; support for additional manufacturing and supply chain development to increase both volume and robustness of supply. RFI reference solicitation number SS_BARDA-2019-01A. Notice details can be found here. To learn more about ASPR/BARDA click here.

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, statements regarding the Request for Information (RFI) and the Request for Proposal (RFP), the threat of bacterial outbreaks, 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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