Achaogen's Plazomicin Highlighted in Multiple Presentations at ASM Microbe 2016 Outlining Bactericidal Activity Against MDR Pathogens

Presentations highlight new data to support plazomicin’s activity against MDR pathogens, biochemical activity, and synergy with other agents against MDR Enterobacteriaceae

SOUTH SAN FRANCISCO, Calif., June 20, 2016 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a clinical-stage biopharmaceutical company developing novel antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today announced data presentations from its plazomicin program at the American Society for Microbiology (ASM) Microbe 2016 Annual Meeting. The Company and its collaborators presented data regarding the Company’s lead product candidate, plazomicin, and its potential to treat serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (CRE).

"The data presented at ASM Microbe continue to demonstrate plazomicin's potent activity against Enterobacteriaceae that are carbapenem-resistant (CRE), which the Centers for Disease Control has labeled a 'nightmare bacteria' since they kill up to half the patients who contract them," said Kenneth Hillan, chief executive officer of Achaogen. "In addition, plazomicin showed superior potency and broader coverage compared with approved aminoglycosides, including activity against aminoglycoside-non-susceptible isolates that harbor common aminoglycoside resistance mechanisms."

The two oral presentations and four posters are summarized as follows:

Occurrence of Aminoglycoside Modifying Enzymes and 16s RNA Methylases Among Enterobacteriaceae and Activity of Plazomicin Against Common Resistance Mechanisms (oral)

M Castanheira, A Davis, T Doyle, R Mendes, R Jones; JMI Laboratories, North Liberty, IA

Dr. Castanheira presented data describing the epidemiology of aminoglycoside resistance and the underlying resistance mechanisms. The data demonstrated plazomicin's potent in vitro activity against aminoglycoside-resistant Enterobacteriaceae.

"These data show that aminoglycoside resistance was driven by one or more aminoglycoside-modifying enzymes in 97.6 percent of the isolates and, importantly, that plazomicin demonstrated potent activity against these aminoglycoside resistant isolates," said Dr. Jones, President and CEO of JMI Laboratories. "I believe further investigation of plazomicin as a new antibiotic for treatment of serious infections due to aminoglycoside-resistant Enterobacteriaceae is warranted."

A Comprehensive Study of Plazomicin Activity Against a Panel of Aminoglycoside Resistance Enzymes (poster)

G Cox, L Ejim, A Sieron, A Serio, K Krause, G Wright; McMaster Univ, Hamilton, ON, Canada, Achaogen, San Francisco, CA

This presentation described new biological and biochemical evidence for the basis of plazomicin activity against aminoglycoside-resistant enterobacteriaceae. Specifically, the study found that plazomicin was not a substrate for the majority of aminoglycoside-modifying enzymes tested, explaining the broad spectrum of activity of plazomicin.

In vitro Activity of Plazomicin Against 110 Carbapenemase-Producing Enterobacteriaceae Clinical Isolates (poster)

Y Zhang, A Kashikar, X Lin, K Bush; Indiana University, Bloomington, IN

This presentation described plazomicin's superior potency compared to other agents against carbapenem-resistant Enterobacteriaceae, including isolates producing KPC, SME and VIM carbapenemases.

Activity of Plazomicin in Combination with Other Antibiotics Against Multidrug Resistant Enterobacteriaceae (poster)

M Thwaites, D Hall, D Shinabarger, A Serio, K Krause, C Pillar; Micromyx, Kalamazoo, MI, Achaogen, San Francisco, CA

This presentation highlighted the potential for plazomicin to act in concert with other agents to efficiently kill bacteria, including MDR isolates. The data showed that combinations of plazomicin with cell wall active agents, such as ceftazidime or piperacillin-tazobactam, kill both aminoglycoside- and carbapenem-resistant Enterobacteriaceae synergistically. Furthermore, no antagonism was observed between plazomicin and any of the agents tested.

"Plazomicin maintained potent activity against multi-drug resistant Enterobacteriaceae including those with characterized resistance to other aminoglycosides. Synergy of plazomicin in combination with piperacillin/tazobactam and with ceftazidime was commonly observed while synergy with the other evaluated agents was also observed for select concentrations and
strains,” said Dr. Pillar, Chief Scientific Officer of Micromyx. “I believe that plazomicin has potential as single or combination therapy for the treatment of serious gram-negative infections caused by multi-drug resistant Enterobacteriaceae.”

Tolerance to Ceftazidime/Avibactam, Plazomicin and Colistin among *Klebsiella pneumoniae* carbapenemase-producing *K. pneumoniae* (oral)

G Haidar, N Clancy, L Chen, B Kreiswirth, H Nguyen; University of Pittsburgh, Pittsburgh, PA, Public Health Research Institute, Newark, NJ

The presentation by Dr. Haider described the rates of tolerance and resistance development by KPC-producing *K. pneumoniae* upon exposure to plazomicin and key comparators. The *K. pneumoniae* strains displayed a low rate of tolerance, and importantly, no resistance to plazomicin after exposure. These results suggest a low potential for tolerance to plazomicin to develop in vitro, which compares favorably to the other studied agents which are currently used for the treatment of CRE, such as ceftazidime-avibactam (Avycaz) and colistimethate sodium (Colistin).

An Evaluation of the Bactericidal Activity of Plazomicin and Comparators Against Multidrug Resistant Enterobacteriaceae (poster)

M Thwaites, D Hall, D Shinabarger, A Serio, K Krause, C Pillar; Micromyx, Kalamazoo, MI, Achaogen, San Francisco, CA

This presentation further demonstrated plazomicin's potent and rapidly bactericidal activity against multi-drug resistant Enterobacteriaceae, including those that are aminoglycoside and carbapenem-resistant.

The abstracts can be accessed through the ASM Microbe website. All posters presented by Achaogen or their collaborators are available as PDF files on the Achaogen website at [www.achaogen.com](http://www.achaogen.com).

About Achaogen

Achaogen is a clinical-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel antibacterials to treat 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. Achaogen's plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority. 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. For more information, please visit [www.achaogen.com](http://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 (i) plazomicin's potential as a single or combination therapy for the treatment of serious gram-negative infections caused by MDR Enterobacteriaceae and (ii) the potential for further investigation of plazomicin as a new antibiotic for treatment of serious infections due to aminoglycoside-resistant Enterobacteriaceae. 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 risk of failure to successfully validate, develop and obtain regulatory clearance or approval for the in vitro diagnostic (IVD) assay for plazomicin; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of commercialization and gaining market acceptance; the risk that bacteria may evolve resistance to plazomicin; risks and uncertainties as to Achaogen's ability to raise additional capital to support the development of plazomicin and its other programs; uncertainties regarding the availability of adequate third-party coverage and reimbursement for newly approved products; Achaogen's reliance on third parties to conduct certain preclinical studies and all of its clinical trials; 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; Achaogen's dependence on its President and Chief Executive Officer; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that BARDA could terminate Achaogen's contract for the funding of the plazomicin development program; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, and its Annual Report on Form 10-K for the fiscal year ended December 31, 2015. 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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