

June 5, 2017

Achaogen Highlights Data Demonstrating Potential of Plazomicin Against MDR Gram-Negative Bacteria at ASM Microbe 2017 Annual Meeting

-- Oral presentations highlighted data from plazomicin Phase 3 EPIC and CARE clinical trials --

-- Newly-released *in vitro* data demonstrated potent activity of plazomicin against contemporary multidrug-resistant *Enterobacteriaceae* isolates --

NEW ORLEANS, June 05, 2017 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a late-stage biopharmaceutical company developing novel antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today announced several presentations that highlighted the potential of plazomicin against MDR gram-negative bacteria in multiple settings. Data were presented at the American Society for Microbiology (ASM) Microbe 2017 Annual Meeting being held in New Orleans, LA from June 1 to 5, 2017.

"With presentations on more than a dozen abstracts, including the positive results from the EPIC and CARE trials, this year's ASM Microbe meeting was a tremendous success for Achaogen and our collaborators - the CARE trial presentation described the reduced mortality in patients with bloodstream infections receiving plazomicin compared to colistin at Day 28 and through long term follow-up at Day 60," said Kenneth Hillan, M.B. Ch.B., Achaogen's Chief Executive Officer. "We also announced, just prior to the meeting, that FDA granted plazomicin Breakthrough Therapy designation for the treatment of BSI caused by certain *Enterobacteriaceae* in patients who have limited or no alternative treatment options. This is a tremendous accomplishment and underscores the need to prioritize potential new treatment options, such as plazomicin, in this setting."

Summary of EPIC and CARE Oral Presentations

Evaluating Once-Daily Plazomicin vs. Meropenem for the Treatment of Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): Results from a Phase 3 Study (EPIC)

D.Cloutier, L.Miller, A.Komirenko, D.Cebrik, T.Keepers, K.Krause, L.Connolly, F.Wagenlehner

The Phase 3 EPIC clinical trial compared plazomicin to meropenem in 609 randomized patients with complicated urinary tract infection (cUTI), including acute pyelonephritis (AP). As previously announced, plazomicin met the objective of non-inferiority compared to meropenem for the U.S. Food and Drug Administration (FDA) primary efficacy endpoints, and achieved statistical superiority for the European Medicines Agency (EMA) primary efficacy endpoints.

New analyses highlighted the efficacy of plazomicin in the subgroup of patients with bacteremia and a statistically higher rate of microbiological eradication in plazomicin-treated patients at the late follow-up visit (LFU) time point (24-32 days from first dose of intravenous study drug):

- 1 Plazomicin demonstrated a favorable composite cure rate at Test of Cure (TOC) compared with meropenem in patients with bacteremia, with composite cure rates of 72.0% vs. 56.5% (difference [plazomicin minus meropenem]: 15.5, 95% CI: -13.7 to 41.9);
- 1 Plazomicin demonstrated significantly higher microbiological eradication rates compared with meropenem at both the TOC and LFU visits. At the TOC visit, microbiological eradication rates were 89.5% vs. 74.6% (difference [plazomicin minus meropenem] 14.9, 95% CI: 7.0 to 22.7). At the LFU visit, microbiological eradication rates were 84.3% vs. 65.0% (difference [plazomicin minus meropenem] 19.3, 95% CI: 10.4 to 27.9).

Plazomicin (PLZ) Associated with Improved Survival and Safety Compared to Colistin (CST) in Serious Carbapenem-Resistant *Enterobacteriaceae* (CRE) Infections: Results of the CARE Study

G.Daikos, L.Connolly, A.Jubb, B.O'Keefe, A.Serio, A.Smith, J.Gall, K.Krause, J.McKinnell, E.Zakynthinos, V.Riddle

The Phase 3 CARE clinical trial compared plazomicin to colistin combination therapy on measures of efficacy and safety in bloodstream infection (BSI) or hospital acquired or ventilator associated bacterial pneumonia (HABP/VABP) due to CRE. Plazomicin demonstrated a lower rate of mortality at Day 28 or serious disease-related complications compared to colistin therapy. Among the 29 patients with BSI included in the microbiological modified intent-to-treat (mMITT) population, the mortality benefit of plazomicin vs. colistin was pronounced (7.1% all-cause mortality in the plazomicin group vs. 40.0% in the colistin group at Day 28, which represents an 82.3% relative reduction) and was maintained through Day 60 (63% reduction in the rate of death through Day 60).

Further analyses highlighted that plazomicin was associated with a higher microbiological response rate compared to colistin and, in terms of key safety outcomes, was associated with a lower incidence and magnitude of serum creatinine increases compared to colistin:

- | In patients with BSI, a favorable microbiological response at the test of cure visit of 92.9% was observed in the plazomicin group vs. 53.3% in the colistin group;
- | The incidence of serum creatinine increases ≥ 0.5 mg/dL above baseline at any time on study was 16.7% in the plazomicin group vs. 50.0% in the colistin group (the serum creatinine elevations in the plazomicin arm of Cohort 1 were all < 1.0 mg/dL while the majority (6/8) of serum creatinine elevations in the colistin arm were ≥ 1.0 mg/dL).

In May 2017, the U.S. Food and Drug Administration granted plazomicin Breakthrough Therapy designation for the treatment of BSI caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options.

Summary of Newly-Released Poster Presentations

In Vitro Activity of Plazomicin and Comparator Agents against Urinary Tract Infection Isolates from the United States and Europe

M. Castanheira, T. Doyle, A. Serio, K. Krause, J. Streit, R. Flamm

This study evaluated the activity of plazomicin and clinically available comparators against isolates collected from UTIs in U.S. and European hospitals, including isolates carrying extended spectrum β -lactamases (ESBLs). The results demonstrate that plazomicin had potent activity against *Enterobacteriaceae*, including β -lactamase-encoding isolates from urinary tract infections.

- | Plazomicin was active against $>95\%$ of the *Enterobacteriaceae* isolates recovered from UTI sources in U.S. and European hospitals;
- | The activity of plazomicin was not affected by the presence of widespread β -lactamase genes among *E. coli* and *K. pneumoniae* isolates.

Aminoglycoside-Resistant Genes among 2014-2015 U.S. Carbapenem-Resistant Enterobacteriaceae Isolates and Activity of Plazomicin Against Characterized Isolates

M. Castanheira, L. Woosley, T. Doyle, A. Serio, K. Krause, R. Flamm

This study evaluated the activity of plazomicin and clinically available aminoglycosides against CRE isolates collected in U.S. hospitals. The results support plazomicin's potential as a treatment for serious infections caused by CRE where treatment options are limited.

- | Plazomicin was active against CRE isolates from U.S. hospitals, including 77 isolates carrying aminoglycoside-modifying enzymes (AMEs) that were resistant to clinically available aminoglycosides.

There were several additional posters presented at the meeting discussing data related to the activity of plazomicin against MDR gram-negative bacteria. All of the posters and the slides from the oral presentations are available on the Achaogen website at www.achaogen.com. In addition, the abstracts can be accessed through the [ASM Microbe website](#).

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 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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