Achaogen Unveils Data Highlighting the Effectiveness of Plazomicin Against MDR Gram-Negative Bacteria at European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)

--- Evaluation of EPIC Phase 3 data demonstrates sustained clinical cure with plazomicin compared to higher clinical relapse rate with meropenem ---

--- 28-Day mortality benefit of plazomicin versus colistin in CARE Phase 3 trial in the bloodstream infection population was pronounced and was maintained through Day 60 follow-up ---

--- Plazomicin demonstrated potent in vitro activity against isolates containing the mobilized colistin resistance (mcr-1) gene ---

SOUTH SAN FRANCISCO, Calif., April 24, 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 multiple presentations that highlight the effectiveness of plazomicin against MDR gram-negative bacteria in multiple settings. Results were presented at the European Congress of Clinical Microbiology and Infectious Disease (ECCMID) which is being held in Vienna, Austria from April 22-25, 2017.

"Gram-negative infections with resistance to currently available antibiotics represent a serious and growing threat to hospitalized patients," said James A. McKinnell, M.D., Assistant Professor of Medicine at the David Geffen School of Medicine and LA Biomed at Harbor-UCLA. "The EPIC trial showed a lower clinical relapse rate for plazomicin compared to meropenem in cUTI and a mortality benefit for plazomicin compared to colistin in the CARE trial. Plazomicin represents an important potential option against the serious threat we face in our hospitals."

"The incidence of colistin-resistant Enterobacteriaceae has been growing steadily, including strains carrying the mcr-1 gene which can make bacteria resistant to colistin, a last-resort drug for some MDR infections," said Patrice Nordmann, M.D., Ph.D., Professor of Medicine, Chair of Microbiology, Department of Medicine, and head of the Emerging Antibiotic Resistance Unit and of the Foreign Research Unit INSERM (Paris, France) at the University of Fribourg (Switzerland) a Senior Consultant at the Institute of Microbiology, University Hospital Center and University of Lausanne, Switzerland. "I am very encouraged by plazomicin’s activity against CRE and also with today’s in vitro data that demonstrated the activity of plazomicin against a large collection of colistin-resistant Enterobacteriaceae."

The following data were presented during a late-breaking oral session on Saturday, April 22, 2017:

Plazomicin versus Meropenem for the Treatment of Complicated Urinary Tract Infection (cUTI) and Acute Pyelonephritis (AP): Results of the EPIC Study

Cloutier DJ, Miller LG, Komirenko AS, Cebrik DS, Krause KM, Keepers TR, Connolly LE, Wagenlehner FME

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

Additional analyses highlight the efficacy of plazomicin in important patient subgroups and at the late follow up time point (24-32 days from first dose of intravenous study drug):

- Plazomicin demonstrated superior microbiological eradication rates at test-of-cure (TOC) in both cUTI and AP subgroups. In patients with cUTI, the treatment difference in favor of plazomicin was 13.7% (95% CI, 3.1 to 24.1) and in patients with AP, the treatment difference in favor of plazomicin was 17.5% (95% CI, 5.5 to 29.5).
- A lower rate of clinical relapse at the late follow up (LFU) visit was observed for plazomicin. The clinical relapse rate was 1.8% for plazomicin vs. 7.9% for meropenem. Importantly, meropenem-treated patients with asymptomatic bacteriuria at the TOC visit had a higher likelihood of clinical relapse at the LFU visit.
- EPIC included an optional switch from intravenous to oral therapy. Efficacy by subgroups of patients who either did or did not receive oral switch therapy was presented. In the subgroup receiving intravenous only therapy the magnitude of the treatment benefit favoring plazomicin was consistent with the primary efficacy results, indicating that the oral antibiotic was unlikely to account for the observed superiority of plazomicin over meropenem at TOC.
Plazomicin (PLZ) Associated with Improved Survival and Safety Compared to Colistin (CST) in Serious Carbapenem-Resistant Enterobacteriaceae (CRE) Infections: Results of the CARE Study

Connolly LE, Jubbi AM, O'Keefe B, Serio AW, Smith A, Gall J, Riddle V, Krause KM, McKinnell JA, Zakynthinos E, Daikos G

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 or serious disease-related complications compared with colistin therapy at Day 28 (50% in the colistin group versus 23.5% in the plazomicin group, which represents a 53% relative reduction). The CARE trial (cohort 1) enrolled predominantly BSI (29) vs HABP/VABP (8) patients. In the BSI population, the mortality benefit of plazomicin versus colistin was pronounced and was maintained to Day 60.

- In patients with BSI, all-cause mortality or significant complications at Day 28 was 53.3% in the colistin group versus 14.3% in the plazomicin group which represents a 73.2% relative reduction.
- Plazomicin-based therapy was associated with a 63% reduction in the rate of death in BSI patients through Day 60 compared with colistin-based therapy, with an estimated hazard ratio (plazomicin:colistin) of 0.37 (90% CI: 0.15, 0.91).

The following data will be presented during a poster session today:

In vitro activity of plazomicin against colistin-resistant Enterobacteriaceae including plasmid-encoded MCR-1-producing isolates

Tendon VD, Connolly LE, Krause KM, Nordmann P

This study evaluated the activity of plazomicin and comparator antibiotics against 95 colistin-resistant clinical Enterobacteriaceae isolates collected from 10 hospitals in eight countries. Plazomicin demonstrated greater activity against these isolates, including those expressing the mcr-1 gene, compared to the other aminoglycosides under evaluation.

- Plazomicin inhibited 89.5% and 93.7% of the colistin-resistant Enterobacteriaceae isolates at ≤2 and ≤4μg/mL, respectively.

There are several additional posters at the meeting discussing data related to the effectiveness of plazomicin against MDR gram-negative bacteria. All of the posters and the presentation slides from the late-breaking oral session are available on the Achaogen website at [www.achaogen.com](http://www.achaogen.com).

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. 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. HHSEO100201000046C. 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](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 potential regulatory approval of plazomicin and Achaogen's commercial objectives. 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 results, performance or achievements expressed or implied by the forward-looking statements, including but not limited to 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; and the risk when bacteria will evolve resistance to plazomicin. 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. 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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