Achaogen Submits Marketing Authorization Application to the European Medicines Agency for Plazomicin

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-- MAA submission for complicated urinary tract infections (cUTI), bloodstream infections, and infections due to Enterobacteriaceae in adult patients with limited treatment options --

SOUTH SAN FRANCISCO, Calif., Oct. 17, 2018 (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 the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for plazomicin. The Company is seeking approval for the following indications:

- Complicated urinary tract infections (cUTI), including pyelonephritis,
- Bloodstream infections (BSI) due to certain Enterobacteriaceae and
- Infections due to Enterobacteriaceae in adult patients with limited treatment options

Plazomicin is marketed as ZEMDRI™ inthe United States and was approved by the U.S. Food and Drug Administration (FDA) in June 2018 as a once-daily aminoglycoside for use in adults with cUTI, including pyelonephritis, due to certain Enterobacteriaceae.

"Our mission is to bring much-needed antibiotics to patients globally and, with this MAA submission, we are one step closer to that goal," said Blake Wise, Achaogen's Chief Executive Officer. "We look forward to the acceptance of this application and the potential to bring a new treatment option to EU patients and healthcare professionals who face the daily challenge of treating recurrent and resistant gram-negative infections."

The MAA is supported by data from both the EPIC (Evaluating Plazomicin In cUTI) and CARE (Combating Antibiotic-Resistant Enterobacteriaceae) clinical trials. EPIC was the first randomized controlled study of once-daily aminoglycoside therapy for the treatment of cUTI, including pyelonephritis. CARE was the first-of-its-kind investigation looking at the efficacy and safety of plazomicin in patients with serious infections due to carbapenem-resistant Enterobacteriaceae (CRE).

About cUTI
cUTI is defined as a urinary tract infection occurring in a patient with an underlying complicating factor of the genitourinary tract, such as a structural or functional abnormality.[1] Patients with pyelonephritis, regardless of underlying abnormalities of the urinary tract, are considered a subset of patients with cUTI.[2] An estimated 3.5 million cases of cUTI are treated in the hospital setting in the EU-5 each year.[3] Enterobacteriaceae are the most common pathogens causing cUTIs[4], and resistance within this family is a global concern. High rates of resistance to previous mainstays of therapy necessitate alternative treatment options. Ineffectively managed cUTI can lead to increased treatment failure rates, recurrence of infection, increased re-hospitalization, and increased morbidity and mortality. cUTI infections place an economic burden on hospitals and payers.[4,5]

About Multi-Drug Resistant (MDR) Gram-Negative Infections
Multidrug resistant gram-negative bacteria, including carbapenem-resistant Enterobacteriaceae (CRE), are a type of gram-negative bacteria with resistance to multiple antibiotics. They can cause bacterial infections that pose a serious threat for hospitalized patients. The lack of availability of medicines to treat patients with infections caused by resistant bacteria has become a major problem in recent years. It is estimated that at least 25,000 patients in the European Union die each year from infections due to bacteria that are resistant to many medicines.[6] Patients with MDR infections often have limited or inadequate therapeutic options leading to high rates of mortality.

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 approved by the FDA for use in the United States is ZEMDRI (plazomicin), for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis. 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. Achaogen is also developing a new aminoglycoside program, which is supported by CARB-X. All product candidates are investigational, have not been determined to be safe or efficacious, and have 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, the potential uses and advantages of ZEMDRI, Achaogen 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. 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 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 August 6, 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.

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[1]Nicolle LE. J Infect Dis. 2001;183(Suppl 1):S5-8.
[2]U.S. Food & Drug. Complicated Urinary Tract Infections: Developing Drugs for Treatment Guidance for Industry.https://www.fda.gov/downloads/Drugs/Guidances/ucm070981.pdf. Accessed June 25, 2018.
[3]Decision Resources Disease Epidemiology 2017.
[4]Bader MS et al. Postgrad Med. 2010;122(6):7-15.
[5]Turner RM et al. Clin Ther. 2015;37(9):2037-2047.
[6]Information Session on Antibiotic Resistance held by EMA, September 19, 2017

Source: Achaogen, Inc.

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