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Achaogen Announces Plazomicin Granted QIDP Designation by FDA

SOUTH SAN FRANCISCO, Calif., Jan. 8, 2015 (GLOBE NEWSWIRE) -- Achaogen, Inc. (Nasdaq:AKAO), a clinical-stage biopharmaceutical company developing novel antibacterials to treat multi-drug resistant (MDR) gram-negative infections, today announced that the Company's lead product candidate, plazomicin, has received Qualified Infectious Disease Product (QIDP) designation from the U.S. Food and Drug Administration (FDA). The QIDP designation was created by the Generating Antibiotic Incentives Now (GAIN) Act, which was part of the FDA Safety and Innovation Act (FDASIA) and provides certain incentives for the development of new antibiotics, including priority review and an additional five years of market exclusivity. The FDA granted fast track status for plazomicin in 2012.

Plazomicin is currently in Phase 3 development for the treatment of serious bacterial infections due to MDR Enterobacteriaceae in hospitalized patients with bacteremia or nosocomial pneumonia. Plazomicin has been granted QIDP designation for the indications of hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), complicated intra-abdominal infections (cIAI), complicated urinary tract infections (cUTI), and catheter-related bloodstream infections.

"We appreciate the FDA's recognition that plazomicin is deserving of QIDP status and eligible for the provisions of the GAIN Act," commented Dr. Kenneth Hillan, MB, ChB, Chief Executive Officer of Achaogen. "We are excited by plazomicin's potential to save lives in patients who have serious multi-drug resistant gram-negative infections."

Plazomicin is a novel aminoglycoside antibiotic designed to treat serious gram-negative infections. It has shown potent bactericidal activity in nonclinical studies against important gram-negative pathogens, including carbapenem-resistant Enterobacteriaceae (CRE). Plazomicin is currently being evaluated in a pivotal Phase 3 trial, CARE (Combating Antibiotic Resistant Enterobacteriaceae), for the treatment of bacteremia and nosocomial pneumonia caused by CRE, which is one of the top global threats in infectious disease due to high rates of mortality in infected patients. In 2013, the CDC labeled CRE as "nightmare bacteria" and indicated that CRE poses a public health threat requiring "urgent and aggressive action."

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, the Company's lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including CRE. Through the Special Protocol Assessment procedure, the FDA has agreed that the design and planned analyses of Achaogen's single pivotal Phase 3 trial adequately address objectives in support of a New Drug Application. Achaogen's plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority (BARDA). 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.

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