ACHAOGEN

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Achaogen Announces Positive Top-Line Results from First Clinical Trial of Orally-Administered Antibacterial Candidate C-Scape

-- C-Scape was well tolerated across all doses studied in Phase 1 trial, with no drug-drug interaction between the previously approved compounds when dosed in combination --

-- C-Scape is a combination of ceftibuten and clavulanate and exhibits potent microbiological activity, pre-clinically, against ESBL-producing enterobacteriaceae --

SOUTH SAN FRANCISCO, Calif., Jan. 02, 2018 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a late-stage biopharmaceutical company developing innovative antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today announced positive top-line results from its Phase 1 clinical study of C-Scape. C-Scape was well tolerated across all doses studied in the Phase 1 trial, with no drug-drug interaction between the previously approved compounds when dosed in combination.

The Company also announced that C-Scape is an oral combination of ceftibuten, an approved third generation cephalosporin, and clavulanate, an approved beta-lactamase inhibitor. C-Scape is the Company's second antibacterial candidate being developed for MDR gram-negative infections and has been awarded Qualified Infectious Disease Product (QIDP) status by the U.S. Food and Drug Administration (FDA) for the treatment of complicated urinary tract infections (cUTI), which provides incentives for new antibiotic treatments, including priority review and additional market exclusivity.

"The positive top-line results from this first-in-human clinical trial for C-Scape are supportive of further evaluation and we continue to plan for Phase 3 in 2018. FDA has previously indicated that a single Phase 3 study in cUTI, if successful, would be sufficient for licensure, and we plan to meet with the FDA in early 2018 to seek agreement on the details of our development plan," said Kenneth Hillan, M.B. Ch.B., Achaogen's President, R&D. "Given the need for additional oral antibiotic options for infections due to ESBL-producing Enterobacteriaceae, we plan to pursue a 505(b)(2) development pathway to take advantage of the development studies performed on ceftibuten and clavulanate, the two previously approved component drugs of C-Scape."

ESBL-producing Enterobacteriaceae are often resistant to currently available oral therapies. The lack of adequate oral therapies leads to hospitalization for intravenous therapy. New oral agents with activity against ESBL-producing organisms are needed to reduce hospitalization and reliance on carbapenems. The ultimate goal of the C-Scape development program would be to treat certain MDR infections in the outpatient and possibly step-down settings.

"There is a tremendous need for orally-administered antibiotics with activity against MDR pathogens, such as ESBL-producing Enterobacteriaceae," said Yoav Golan, M.D., M.S., Tufts Medical Center. "For patients suffering from complicated urinary tract infections due to ESBL-producing Enterobacteriaceae, intravenous carbapenem therapy is often their only treatment option. I would welcome a new oral beta-lactam and beta-lactamase inhibitor combination that would help limit use of carbapenems in these patients."

About the Clinical Trial Results
This Phase 1 clinical trial was a double-blind, randomized, placebo-controlled, parallel group study to assess the safety, tolerability and clinical pharmacology of C-Scape, administered orally, in 41 healthy subjects. An overview of the clinical trial data is as follows:

- The combination of ceftibuten and clavulanate was well tolerated when administered for 14 days across all dosing regimens tested.
- No serious adverse events (SAEs), grade 3 or 4 adverse events, or adverse events leading to discontinuation of study drug were observed.
- Safety profile was consistent with expectations for ceftibuten and clavulanate when administered based on existing product labels.
- The most commonly reported adverse events included vascular access site bruising, headache, diarrhea, gastroenteritis and nausea. The incidence of each of the most common adverse events was comparable between the active treatment groups and placebo.

- Preliminary pharmacokinetics following administration of ceftibuten and clavulanate in combination were similar to those following administration of each compound alone, indicating no drug-drug interaction between ceftibuten and clavulanate.

- We continue to evaluate safety and pharmacokinetic data and plan to present these at an upcoming scientific and/or investor meeting.

About the C-Scape Program
C-Scape is a combination of ceftibuten, an approved third generation cephalosporin, and clavulanate, an approved beta-lactamase inhibitor, and is the Company's second antibacterial candidate being developed for MDR gram-negative infections. With the C-Scape program, Achaogen plans for a rapid development and regulatory approach that leverages a 505(b)(2) path that supports the initiation of a single pivotal Phase 3 trial in 2018. C-Scape has been awarded Qualified Infectious Disease Product (QIDP) status by FDA for the treatment of cUTI, including acute pyelonephritis (AP). QIDP designation provides incentives for new antibiotic treatments, including priority review and additional market exclusivity. The Company's preclinical studies have confirmed the potent microbiologic activity against ESBL-producing Enterobacteriaceae of C-Scape and the first-in-human clinical trial suggests its potential to achieve necessary exposures with an oral dosing regimen.

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, its lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. The Food and Drug Administration has granted plazomicin Breakthrough Therapy designation for the treatment of bloodstream infections caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options. Achaogen's plazomicin program has been funded in part with Federal funds from the Biomedical Advanced Research and Development Authority (BARDA). The Company's second product candidate is C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination, is funded, in part with Federal funds from BARDA, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, U.S. Department of Health and Human Services, under Contract No. HHSO100201700021C. Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections and additional disease areas. All product candidates, including plazomicin, 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 plans for clinical development of C-Scape and its 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 or C-Scape; 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 filed on March 14, 2017 and its Quarterly Report on Form 10-Q filed on November 8, 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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