CMS Grants New Technology Add-on Payment to ZEMDRI™ (plazomicin)

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--- Add-on Payment to Provide Additional Medicare Reimbursement up to 50% of the cost of ZEMDRI Prescribed to Medicare patients in Hospital Inpatient Setting ---

SOUTH SAN FRANCISCO, Calif., Aug. 03, 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 that the Centers for Medicare & Medicaid Services (CMS) has granted a new technology add-on payment (NTAP) for ZEMDRI when administered in the hospital inpatient setting.

The NTAP program will provide hospitals with a payment, in addition to the standard-of-care Diagnostic Related Group (DRG) reimbursement, of up to 50% of the cost of ZEMDRI for a period of two to three years, effective in the 2019 fiscal year starting on October 1, 2018. CMS has assigned a maximum payment of $2,722.50 for a patient treated with ZEMDRI. Cases involving ZEMDRI that are eligible for NTAP will be identified by unique ICD–10–PCS procedure codes XW033G4 and XW043G4.

In the final rule concerning Hospital Inpatient Prospective Payment Systems and Fiscal Year 2019 Rates, CMS stated that “ZEMDRI offers a substantial clinical improvement for patients who have limited or no alternative treatment options because it is a new antibiotic that offers a treatment option for a patient population unresponsive to currently available treatments” and that “ZEMDRI meets all the criteria for approval of new technology add-on payments.” Additional information on the final rule and its discussion of NTAP and ZEMDRI can be found online at: **HIPPS.** This document is scheduled to be published in the Federal Register on August 17, 2018.

“Receiving NTAP designation is an important step towards ensuring physician and patient access to ZEMDRI and underscores the importance of ZEMDRI as a new treatment option,” said Blake Wise, CEO of Achaogen. “The NTAP program plays a vital role in providing supplementary reimbursement for ZEMDRI to help reduce unreimbursed costs to hospitals serving Medicare patients.”

About cUTI

cUTI is defined as a UTI 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 million cases of cUTI are treated in the hospital setting in the U.S. 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 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 is ZEMDRI, for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis. The Achaogen ZEMDRI program has been 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. The Company is also developing C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination, which is also supported by BARDA. Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections and additional disease areas. 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, Achaogen expectations regarding the timing of commercial availability of ZEMDRI, 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. Such risks and uncertainties include, among others, the risks and uncertainties of the regulatory approval process; market size and growth; timing of activities, including launch dates of products; statements about the efficacy, safety and tolerability of ZEMDRI; the risks and uncertainties of product sales; the risk of when bacteria will evolve resistance to ZEMDRI; Achaogen's reliance on third-party contract manufacturing organizations for manufacture and supply, including sources of certain raw materials; 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 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 May 7, 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 Landscape & Forecast, Hospital-Treated Gram-Negative Infections, September 2017; data on file.
[4]Bader MS et al. Postgrad Med. 2010;122(6):7-15.
[5]Turner RM et al. Clin Ther. 2015;37(9):2037-2047.

Primary Logo

Source: Achaogen, Inc.