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Venatorx Pharmaceuticals to Present at IDWeek 2023

-New data to be presented from Phase 3 CERTAIN-1 study with Cefepime-Taniborbactam
-MD Anderson Cancer Center analysis of Cefepime-Taniborbactam in vitro activity against clinically significant gram-negative bacteria isolated from patients with cancer

September 27, 2023 08:30 AM Eastern Daylight Time

MALVERN, Pa.--(BUSINESS WIRE)--Venatorx Pharmaceuticals, a private, clinical-stage pharmaceutical company focused on improving health outcomes for patients with multidrug-resistant bacterial infections and hard-to-treat viral infections, today announced seven presentations during IDWeek 2023, October 11-15, 2023, in Boston, MA for its novel antibiotics cefepime-taniborbactam and ceftibuten-ledaborbactam, including:

Presentation Details

Title:	**Oral presentation:** Ceftibuten-Ledaborbactam
Date/Time:	October 14, 2023, 8:00 am – 9:00 am
Session Title:	New Antimicrobials in the Pipeline Part 2
Session Location:	104 ABC
Presenting Author:	Paul McGovern (Venatorx)

Title:	CERTAIN-1 Subgroup Analysis: A Phase 3 Study of Cefepime-Taniborbactam Efficacy in the Treatment of Complicated Urinary Tract Infections (cUTI) (#2513)
Date/Time:	October 14, 2023, 12:15 pm – 1:30 pm
Session Title:	New Antimicrobial Drug Development
Session Location:	Hall B + C
Presenting Author:	Mary Beth Dorr (Venatorx)

Title:	Outcomes by Resistance Phenotype and Genotype among Baseline Pathogen in Patients with Complicated Urinary Tract Infection (cUTI) in the Phase 3 CERTAIN-1 Study (#2523)
Date/Time:	October 14, 2023, 12:15 pm – 1:30 pm
Session Title:	New Antimicrobial Drug Development
Session Location:	Hall B + C
Presenting Author:	Greg Moeck (Venatorx)

Title:	In Vitro Activity of Cefepime-Taniborbactam and Comparators Against Genotypically Characterized Carbapenem-Resistant Enterobacterales (CRE) and Carbapenem-Resistant *Pseudomonas aeruginosa* (CRPA) from the United States, 2018-2021 (#2150)
Date/Time:	October 14, 2023, 12:15 pm – 1:30 pm
Session Title:	Antibiotic Novel Agents
Session Location:	Hall B + C
Presenting Author:	Mark Wise (IHMA)

Title:	Antimicrobial Activity of Cefepime in Combination with Taniborbactam Against Resistant Clinical Isolates from the United States 2018-2021 (#2129)
Date/Time:	October 14, 2023, 12:15 pm – 1:30pm
Session Title:	Antimicrobial Novel Agents
Session Location:	Hall B + C
Presenting Author:	Meredith Hackel (IHMA)

Title:	In vitro activity of aztreonam-avibactam (ATM-AVI), cefiderocol (FDC), and cefepime-taniborbactam (FEP-TAN) against multi-species, NDM-producing Enterobacterales causing a local outbreak (#2185)
Date/Time:	October 14, 2023, 12:15 pm – 1:30pm
Session Title:	Antimicrobial Resistance Mechanisms

Session Location: Hall B + C

Presenting Author: Ellen G. Kline (University of Pittsburg)

Title: *In Vitro* Activity of Cefepime-Taniborbactam Against Clinically Significant Gram-Negative Bacteria Isolated from Patients with Cancer (#2122)

Date/Time: October 14, 2023, 12:15 pm – 1:30pm

Session Title: Antimicrobial Novel Agents

Session Location: Hall B + C

Presenting Author: Bahgat Gerges (MD Anderson UT)

About the CERTAIN-1 Phase 3 Clinical Trial

CERTAIN-1 (Cefepime Rescue with Taniborbactam in cUTI) was a global, randomized, double-blind, active-controlled non-inferiority Phase 3 study evaluating the efficacy, safety, and tolerability of cefepime-taniborbactam compared to meropenem in adults with cUTI, including acute pyelonephritis. The trial enrolled 661 adult patients who were randomized 2:1 to receive cefepime-taniborbactam 2.5g q8h or meropenem 1g q8h for 7 days (up to 14 days for patients with bacteremia). The primary efficacy endpoint evaluated the composite clinical and microbiologic response (i.e., bacterial eradication) at the Test of Cure (TOC) visit (Day 19-23) in the microbiological intent-to-treat (microITT) population.

Cefepime-taniborbactam met the primary efficacy endpoint of statistical noninferiority (NI) to meropenem in the microITT population at TOC with composite microbiologic and clinical success occurring in 70.6% of cefepime-taniborbactam treated patients and 58.0% of meropenem treated patients (treatment difference 12.6; 95% CI, 3.1, 22.2). A prespecified superiority assessment was conducted following confirmation of NI. The superiority of cefepime-taniborbactam was concluded as the lower bound of the 95% CI for noninferiority was greater than zero. The pre-specified superiority test (two-sided p-value = 0.0088) demonstrated the strength of evidence associated with the superiority conclusion for the composite endpoint at TOC. The superiority of cefepime-taniborbactam was sustained for the composite microbiologic and clinical response at the Late-Follow-Up (Day 28-35) visit.

Rates of treatment-emergent adverse events (TEAEs) were 35.5% for cefepime-taniborbactam and 29.0% for meropenem. Serious TEAEs occurred in 2.0% and 1.8% of cefepime-taniborbactam and meropenem treated patients, respectively. Treatment discontinuations due to TEAEs occurred in 3.0% of cefepime-taniborbactam patients and 0.9% of meropenem treated patients. There was one death in the cefepime-taniborbactam treatment group, which was unrelated to study treatment as assessed by the investigator.

About Cefepime-Taniborbactam

Cefepime-taniborbactam is an investigational intravenous (IV) beta-lactam/beta-lactamase inhibitor (BL/BLI) antibiotic combination being developed for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP). The New Drug Application for cefepime-taniborbactam was accepted for review by the US FDA for cUTI, including pyelonephritis with a PDUFA date of February 22, 2024.

Cefepime, a fourth-generation cephalosporin, is a widely used beta-lactam (BL) antibiotic with more than two decades of proven safety and clinical utility against susceptible gram-negative and gram-positive bacteria. Taniborbactam is a beta-lactamase inhibitor (BLI) that, in combination with cefepime, is being studied as a potential treatment option for patients with serious bacterial infections caused by antibiotic resistant gram-negative bacteria, most notably extended spectrum beta-lactamase (ESBL)-expressing Enterobacterales, carbapenem-resistant Enterobacterales (CRE), and multidrug-resistant (MDR) *Pseudomonas aeruginosa* (MDR-PA), which can include carbapenem-resistant *P. aeruginosa* (CRPA).

Cefepime-taniborbactam has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the U.S. Food and Drug Administration (FDA).

About Ceftibuten-Ledaborbactam Etzadroxil

Ceftibuten, an oral third-generation, highly bioavailable cephalosporin antibiotic, is approved for the treatment of upper and lower respiratory tract infections and urinary tract infections. Ledaborbactam etzadroxil is a novel broad-spectrum boronic acid beta-lactamase inhibitor (BLI). *In vitro* and *in vivo* studies demonstrated that ledaborbactam restores the activity of ceftibuten against strains of Enterobacterales expressing Ambler class A ESBLs, class C cephalosporinases, and class A & D serine carbapenemases (KPC and OXA-48, respectively) as well as multidrug-resistant (MDR) Enterobacterales. Ceftibuten-ledaborbactam etzadroxil may offer a new treatment option for outpatient therapy to treat serious bacterial infections caused by MDR Enterobacterales that are resistant to current standard-of-care oral and intravenous antibiotics, including fluoroquinolones, trimethoprim-sulfamethoxazole, cephalosporins and carbapenems.

Ceftibuten-Ledaborbactam etzadroxil has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the U.S. Food and Drug Administration (FDA).

Funding Partners and Collaborators

Development of cefepime-taniborbactam began with federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services under contract number HHSN272201300019C, and Wellcome Trust under award number 360G-Wellcome-101999/Z/13/Z, and continues with federal funds from the Biomedical Advanced Research and Development Authority, Administration for Strategic Preparedness and Response, Department of Health and Human Services under contract numbers HHSO100201900007C and 75A50122C00080.

In September 2018, Venatorx entered into an exclusive license agreement with Everest Medicines to support the development, registration, and commercialization of cefepime-taniborbactam in People's Republic of China, Macau, Hong Kong, Taiwan, South Korea, and select countries in Southeast Asia (the "Territory").

In April 2020, Venatorx and GARDP announced a collaboration to accelerate the development of, and access to, cefepime-taniborbactam for adult and pediatric populations. Venatorx has granted GARDP exclusive rights to distribute and sub-distribute cefepime-taniborbactam, once it is approved for clinical use, in low- and lower middle-income countries.

Ceftibuten-ledaborbactam etzadroxil is funded in whole or in part by the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services under contract number HHSN272201600029C.

About Venatorx Pharmaceuticals, Inc.

Venatorx is a private, pre-commercial pharmaceutical company focused on improving health outcomes for patients with difficult-to-treat drug resistant gram-negative bacterial infections and viral infections. Venatorx's lead asset, cefepime-taniborbactam, is an investigational antibiotic that completed a Phase 3 study (NCT03840148) in adults with complicated urinary tract infections (cUTI), including pyelonephritis and is under FDA review with a PDUFA action date of February 22, 2024. In October 2022, BARDA awarded a contract of up to $318M to Venatorx for development and procurement of cefepime-taniborbactam for the treatment of melioidosis and multidrug-resistant infections. As part of its broader pipeline, Venatorx is also developing an oral antibacterial, ceftibuten-ledaborbactam etzadroxil, that recently completed multiple Phase 1 clinical studies and is expected to begin global Phase 3 testing in 2Q2025. For more information about Venatorx and its anti-infectives portfolio, please visit www.venatorx.com.

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