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Venatorx Pharmaceuticals Presents Data on Investigational Cefepime-Taniborbactam at IDWeek 2022

Superior to Meropenem for the Primary Efficacy Endpoint

Safety Profile Consistent with Meropenem

Malvern, PA, October 20, 2022 – Venatorx Pharmaceuticals, a private, clinical-stage pharmaceutical company focused on improving health outcomes for patients with difficult-to-treat drug resistant gram-negative bacterial infections and viral infections, today will present new data during IDWeek 2022 for its novel investigational antibiotic cefepime-taniborbactam. Two oral presentations will showcase cefepime-taniborbactam and highlight the safety and efficacy results from the recently completed pivotal Phase 3 complicated urinary tract infection clinical trial, CERTAIN-1. The presentations, along with the four other posters detailing additional cefepime-taniborbactam data at IDWeek 2022 (see release), will be available on the company's website.

"We are very encouraged by the results of the CERTAIN-1 trial assessing the efficacy and safety of cefepime-taniborbactam. We believe this data is meaningful given the sustained clinical benefit versus meropenem up to 3 to 4 weeks after treatment," said Christopher J. Burns, Ph.D., President and CEO of Venatorx. "We believe these data will support our planned New Drug Application submission of cefepime-taniborbactam for complicated urinary tract infections in the first half of next year and could help to address the devasting impact on patient lives from the growing global pandemic of difficult-to-treat drug-resistant gram-negative bacterial infections."

About CERTAIN-1

CERTAIN-1 is a randomized, multicenter, double-blind, active-controlled, non-inferiority study of hospitalized patients (N=661) with complicated urinary tract infections (cUTI), including acute pyelonephritis (AP), comparing cefepime-

taniborbactam (2.5g every 8 hours) to meropenem (1g every 8 hours). The primary endpoint was the composite microbiologic and clinical response at the Test of Cure (TOC) visit (Day 19-23) in the microbiological intent to treat (microITT) population. The non-inferiority margin was set at 15% and there was a prespecified superiority test if non-inferiority was concluded.

Efficacy Data

In the main presentation titled, "CERTAIN-1: A Phase 3 Study of Cefepime-Taniborbactam Efficacy and Safety in the Treatment of Complicated Urinary Tract Infections (cUTI), including Acute Pyelonephritis (AP)," cefepime-taniborbactam met the prospectively defined non-inferiority primary endpoint of composite microbiologic and clinical response versus meropenem at the TOC visit (70.6% response rate for cefepime-taniborbactam versus 58.0% for meropenem). The prespecified superiority analysis at the TOC visit demonstrated that cefepime-taniborbactam was statistically superior to meropenem for the composite endpoint (response rate difference: 12.6 [CI: 3.1, 22.2]; p=0.0088) and for the microbiologic endpoint (response rate difference: 11.7% [CI: 2.9, 21.0]; p=0.0085); the clinical endpoint response rate difference was 4.5% [CI: -2.6, 12.6]. At the late follow-up (LFU) visit (Day 28-35), cefepime-taniborbactam demonstrated sustained statistical superiority to meropenem for the composite endpoint (63.8% response rate for cefepime-taniborbactam versus 51.7% for meropenem (response rate difference: 12.1 [CI: 2.2, 21.9]; p=0.0157) and for the clinical response endpoint (response rate difference: 9.9 [CI: 1.5, 18.8; p=0.0192); the microbiologic endpoint response rate difference was 7.7% [CI: -1.6, 17.3]. Additionally, cefepime-taniborbactam maintained a numerical advantage to meropenem against resistant pathogens: cefepime-resistant (70.8% response rate for cefepime-taniborbactam versus 53.3% for meropenem), ESBL-producing (68.8% response rate for cefepime-taniborbactam versus 57.1% for meropenem) and MDR (67.0% response rate for cefepime-taniborbactam versus. 58.9% for meropenem).

Safety Data

Cefepime-taniborbactam demonstrated a safety profile consistent with meropenem. Treatment-Emergent Adverse Events occurred in 35.5% and 29.0% of cefepime-taniborbactam and meropenem treated patients respectively. Serious adverse events occurred in 2.0% of cefepime-taniborbactam patients and 1.8% of meropenem treated patients. The most frequently reported treatment-emergent adverse events were headache (6.1% with cefepime-taniborbactam versus 3.7% for meropenem), diarrhea (4.1% versus 2.3%), constipation (3.2% versus 1.4%), hypertension (2.3% versus 0.9%), nausea (2.0% versus 0.9%), and alanine aminotransferase increased (0.9% versus 2.3%). Three percent of patients treated with cefepime-taniborbactam

discontinued therapy due to a treatment-emergent adverse event versus 0.9% of patients treated with meropenem. The safety data for cefepime-taniborbactam was consistent with the historical safety data for cefepime.

About Cefepime-Taniborbactam
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) with broad coverage of both serine- and metallo-beta-lactamases. In combination with cefepime, taniborbactam may offer a new treatment option for patients with serious bacterial infections caused by difficult-to-treat drug resistant gram-negative bacteria, most notably carbapenem-resistant Enterobacterales (CRE) and carbapenem-resistant or multi-drug resistant Pseudomonas aeruginosa (CRPA/MDR-PA), and other severe or rare infections.

Cefepime-taniborbactam recently completed a Phase 3 study (CERTAIN-1) in adults with cUTI, including pyelonephritis. In this study, cefepime-taniborbactam met the primary noninferiority efficacy endpoint at Test-of-Cure visit and furthermore demonstrated statistical superiority to the comparator, meropenem. In addition, cefepime-taniborbactam demonstrated a safety profile similar to meropenem. Based on positive results from the CERTAIN-1 clinical trial, Venatorx expects to submit a New Drug Application to the FDA for cefepime-taniborbactam in the first half of 2023. Cefepime-taniborbactam has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designation by the U.S. Food and Drug Administration (FDA). In October 2022, BARDA awarded a contract of up to $318M for development and procurement of cefepime-taniborbactam for the treatment of melioidosis and multi-drug resistant infections.

Funding Partners and Collaborators for Cefepime-Taniborbactam
This project has been funded in part 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 No. 360G-Wellcome-101999/Z/13/Z, and has continued with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, 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 Greater China, South Korea, and select countries in Southeast Asia. Everest will be solely responsible for the commercialization of cefepime-taniborbactam in its territory and Venatorx will be eligible to receive royalties on net sales.

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.

About Venatorx Pharmaceuticals
Venatorx is a private, late-stage clinical pharmaceutical company focused on improving health outcomes for patients with multidrug-resistant bacterial infections and hard-to-treat viral infections. Venatorx's lead program, cefepime-taniborbactam, is a clinical-stage antibiotic that completed a Phase 3 study in adults with complicated urinary tract infections (cUTI), including pyelonephritis. Based on positive results from the CERTAIN-1 Phase 3 clinical trial, the Company expects to submit a New Drug Application with the U.S. Food and Drug Administration for cefepime-taniborbactam in the first half of 2023. In October 2022, BARDA awarded a contract of up to $318M for development and procurement of cefepime-taniborbactam for the treatment of melioidosis and multi-drug resistant infections. Venatorx is also developing an oral antibacterial, ceftibuten-ledaborbactam (formerly known as VNRX-7145), for the treatment of cUTI, including pyelonephritis, caused by certain bacteria in adult patients with limited treatment options; this product is nearing completion of Phase 1. For more information about Venatorx and its anti-infectives portfolio, please visit www.venatorx.com.

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