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Venatorx Pharmaceuticals Provides Update on Cefepime-Taniborbactam

Topline Data from Phase 3 clinical trial of cefepime-taniborbactam in patients with complicated urinary tract infections (cUTIs) expected first quarter 2022

BARDA extends cost-sharing contract to support the development of cefepime-taniborbactam in patients with hospital acquired bacterial pneumonia and ventilator associated bacterial pneumonia (HABP/VABP)

Phase 3 clinical trial of cefepime-taniborbactam in patients with HABP/VABP scheduled to begin in 2022

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MALVERN, Pa.--(BUSINESS WIRE)--Venatorx Pharmaceuticals today announced a comprehensive update about cefepime-taniborbactam, the Company's intravenous beta-lactam / beta-lactamase inhibitor (BL/BLI) combination antibiotic that is being developed for the treatment of complicated urinary tract infections (cUTIs) and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).

"The emergence and global spread of multi-drug-resistant pathogens, particularly in gram-negative bacteria, has caused alarm within the medical community due to the high mortality rate associated with infections caused by these hard-to-treat pathogens," said Christopher J. Burns, Ph.D., President and CEO of Venatorx. "We are particularly concerned about the emergence and spread of bacteria that carry metallo-beta-lactamases (MBLs), which started in Asia, have become endemic in Southern and Eastern Europe, and are now being identified in hospitals and long-term care facilities in the United States. Novel antibacterial therapies, such as cefepime-taniborbactam, are needed to effectively tackle these superbugs. We believe that our broad-spectrum agent may represent a significant improvement over standard of care antibiotics and supports global health efforts to combat antibiotic-resistant infections."

Cefepime, a fourth-generation cephalosporin, is a trusted first-line agent with more than two decades of proven safety and clinical utility against susceptible gram-negative and positive bacteria. Taniborbactam (formerly VNRX-5133) is an injectable BLI that, in combination with cefepime, is a potential treatment option for patients with serious bacterial infections caused by resistant gram-negative bacteria. Cefepime-taniborbactam has *in vitro* and *in vivo* activity against difficult-to-treat resistant pathogens, including carbapenem-resistant Enterobacterales (CRE) and carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) that produce extended-spectrum beta-lactamases (ESBL), AmpC beta-lactamases, oxacillinases (OXA), *Klebsiella pneumonia* carbapenemase (KPC), and metallo-beta-lactamases including Verona integron-encoded (VIM) and New Delhi metallo-beta-lactamases (NDM).

Qualified Infectious Disease Product and Fast Track Designations

The U.S. Food and Drug Administration (FDA) has granted cefepime-taniborbactam Qualified Infectious Disease Product (QIDP) and Fast Track designations for the treatment of cUTI and HABP/VABP. Fast Track designation is designed to facilitate the development, and to expedite the review of drugs to treat serious conditions that do not have sufficient treatment options. QIDP designation provides certain incentives for the development of new antibiotics, including priority review, as well as a five-year regulatory exclusivity extension. QIDP was authorized under the Generating Antibiotic Incentives Now (GAIN) Act of 2012, as part of the FDA Safety and Innovation Act, to underscore the urgency in development of new antibiotics.

Phase 3 CERTAIN-1 study targeting cUTI Infections

Cefepime-taniborbactam is being evaluated in a global randomized, double-blind, active-controlled, non-inferiority phase 3 study called CERTAIN-1 (Cefepime Rescue with Taniborbactam in cUTI) (ClinicalTrials.gov – NCT03840148) in adults with cUTI, including acute pyelonephritis. The trial is assessing the efficacy, safety and tolerability of cefepime-taniborbactam compared to meropenem using clinical cure and microbiologic eradication as the primary composite efficacy endpoint. Venatorx expects to report topline results in the first quarter of 2022.

Phase 3 CERTAIN-2 study targeting HABP/VABP Infections

In addition to cUTI, Venatorx is pursuing HABP/VABP indication for cefepime-taniborbactam and is targeting study start in 2022.

Today, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, announced an extension of the contract with Venatorx to support the development and studies needed for marketing authorization of cefepime-taniborbactam to treat HABP/VABP. Venatorx and BARDA will share the costs of the HABP/VABP clinical trial including site activation, patient enrollment, and completion.

Pediatric Investigation Plan (PIP)

The FDA and the EMA approved Venatorx's initial Pediatric Study Plan (iPSP) and Pediatric Investigation Plan (PIP), respectively, for cefepime-taniborbactam. The PIP approvals enable Venatorx and its partner, the Global Antibiotic Research and Development Partnership (GARDP), to initiate clinical trials for cefepime-taniborbactam in pediatric patients, including newborns. In support of the PIP and iPSP, juvenile toxicology dose ranging finding studies for cefepime-taniborbactam are ongoing.

Funding Partners and Collaborators

This project 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 The Wellcome Trust under Award No. 360G-Wellcome-101999/Z/13/Z, and continues with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under contract number HHSO100201900007C.

In September 2018, Venatorx entered into an exclusive license agreement with Everest Medicines Limited (HKEX:1952.HK) to support the development, registration and commercialization of cefepime-taniborbactam in Greater China, South Korea and Southeast Asia. Under the terms of the license agreement, Venatorx and Everest are collaborating on the global Phase 3 clinical development trials of cefepime-taniborbactam. Everest will be solely responsible for the commercialization of cefepime-taniborbactam in its territory for which 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. GARDP is collaborating with Venatorx to complete the development of cefepime-taniborbactam, including the Phase 3 cUTI trial, an additional clinical trial in adults with infections due to carbapenem-resistant Enterobacterales and Pseudomonas, and non-clinical and clinical development activities to enable cefepime-taniborbactam to be used for children, including newborns with serious bacterial infections. Venatorx is committed to

working with GARDP to distribute cefepime-taniborbactam on an affordable basis worldwide. Venatorx has granted GARDP exclusive rights to distribute and sub-distribute cefepime-taniborbactam, once it is approved for clinical use, in most low- and lower middle-income countries.

About Venatorx Pharmaceuticals

Founded in 2010, Venatorx Pharmaceuticals is a private, clinical-stage pharmaceutical company focused on improving health outcomes for patients with multi-drug-resistant bacterial infections and hard-to-treat viral infections. Venatorx has built a world-class in-house research and development organization that has filed over 120 patents. Venatorx's two lead antibacterial clinical-stage programs are intravenous (cefepime-taniborbactam) and oral (ceftibuten/VNRX-7145) broad-spectrum beta-lactam / beta-lactamase inhibitor combinations that are in Phase 3 and Phase 1, respectively. In addition, the first Venatorx antiviral compound (VNRX-9945), a Hepatitis B virus inhibitor, is in Phase 1 clinical development. The Company also has discovery-stage programs targeting a novel class of non-beta-lactam antibiotics called Penicillin Binding Protein (PBP) inhibitors that have the potential to circumvent 70+ years of resistance and usher in a new wave of antibacterial therapeutics. For more information about Venatorx, please visit www.venatorx.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the potential, safety, efficacy, and regulatory and clinical development of Venatorx Pharmaceuticals' product candidates.

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