Venatorx Pharmaceuticals Awarded BARDA Project BioShield Contract

Total award of up to $318M for development and procurement of novel antibiotic cefepime-taniborbactam for the treatment of melioidosis and multi-drug resistant infections

Malvern, PA, October 3, 2022 – Venatorx Pharmaceuticals, 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, today announced the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services (HHS), has awarded the company a contract to support the development of cefepime-taniborbactam for the treatment of melioidosis. The contract also includes options to procure cefepime-taniborbactam for national preparedness efforts.

The contract with BARDA leverages the 2004 Project BioShield Act, that enabled acceleration of the research, development, purchase, and availability of effective medical products against chemical, biological, radiological, or nuclear agents.

“We thank BARDA, ASPR, and HHS for their dedication to scientific innovation and commitment to this private-public partnership. The contract supports Venatorx’s mission to address the devasting impact on patient lives from the growing multidrug-resistant bacterial infections in the U.S.,” said Christopher J. Burns, Ph.D., President and CEO of Venatorx. “Venatorx and cefepime-taniborbactam can play an important role in helping to enhance the biodefense preparedness of our country, save lives and protect Americans. We are confident that cefepime-taniborbactam is extremely well-positioned to help address potential public health emergencies as increasing antibiotic multi-drug resistant infections continue to represent a global threat.”

Terms of the Award

This project has been funded in whole or in part with Federal funds from the Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, under contract number 75A50122C00080. Under the terms of the agreement, Venatorx may receive up to $318M in development funding and potential product procurement. BARDA will initially award approximately $72M for the development of cefepime-taniborbactam, including completion of a clinical study in HABP/VABP, CMC development, post-marketing commitments, nonclinical studies, and submission of a pre-EUA package to FDA for melioidosis. Based on milestone achievements, Venatorx may receive additional funding of up to approximately $67M for further development of cefepime-taniborbactam, including a melioidosis clinical study, and up to $179M for product procurement.

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 complicated urinary tract infections (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 was well-tolerated with a similar safety profile 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).

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 number HHSO100201900007C.

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, 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. 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.

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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