VenatoRx Pharmaceuticals Initiates Enrollment in Phase 3 Trial of Cefepime/VNRX-5133 in Patients with Complicated Urinary Tract Infections

Demonstrated potent activity against carbapenem-resistant Enterobacteriaceae* and *carbapenem-resistant Pseudomonas aeruginosa

VNRX-5133 may provide a therapeutic option for these emerging pathogens, which are classified as urgent public health threats by the Centers for Disease Control and Prevention

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MALVERN, Pa.--(BUSINESS WIRE)--VenatoRx Pharmaceuticals today announced that it has initiated enrollment in its Phase 3 trial of cefepime/VNRX-5133 in patients with complicated urinary tract infections (cUTIs).

VNRX-5133 is an injectable beta-lactamase inhibitor (BLI) that features selective and potent *in vitro* activity against both serine- and metallo-beta-lactamases (MBLs), including ESBL, OXA, KPC, NDM, and VIM enzymes. VenatoRx believes that VNRX-5133, in a fixed combination with the fourth generation cephalosporin, cefepime, has the potential to provide a valuable broad-spectrum treatment option to meet unmet medical needs in patients with infections due to carbapenem-resistant pathogens including carbapenem-resistant Enterobacteriaceae (CRE) and carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), suspected polymicrobial infections caused by both gram-negative and gram-positive susceptible pathogens, and engineerable bioterror pathogens such as *Burkholderia* spp.

This Phase 3 clinical trial (ClinicalTrials.gov - NCT03840148) is a global randomized, double-blind, active controlled, non-inferiority study evaluating the efficacy, safety, and tolerability of cefepime/VNRX-5133 in adults with cUTI, including acute pyelonephritis. The trial will assess the safety and efficacy of cefepime/VNRX-5133 as compared with that of meropenem using clinical cure and microbiological eradication as the primary composite efficacy endpoint. VenatoRx expects to enroll 582 patients for this study, and top-line results are expected by the end of 2020.

“Initiating this Phase 3 clinical trial is an important milestone for VenatoRx as well as future development of our novel anti-infective clinical candidate,” said Christopher J. Burns, Ph.D., President and CEO of VenatoRx. “The need for effective new therapies for complicated CRE infections is clear based upon the CDC’s estimates that antibiotic-resistant infections affect at least two million people in the United States, alone, and drive $35 billion in healthcare system costs, annually. We wouldn’t be where we are today without NIAID, The Wellcome Trust, BARDA and our private equity investors. We thank them, along with the investigators and patients who have participated, and will participate, in this and future studies, for their continued support and confidence in our development program.”

Preclinical results showed that cefepime/VNRX-5133 showed potent *in vitro* activity against all Enterobacteriaceae, with an MIC_{90} of 0.5 mg/L, compared to cefepime, levofloxacin, meropenem, and piperacillin-tazobactam (MIC_{90} values >128, >4, 4, >64 mg/L, respectively). Cefepime/VNRX-5133 inhibited 99% of all Enterobacteriaceae at the cefepime dose dependent breakpoint of ≤8 mg/L, including 99% of ESBL-producers and 93% of meropenem-non-susceptible (CRE) isolates. Cefepime/VNRX-5133 was the most active compound tested against *P. aeruginosa*, including serine beta-lactamase and MBL-producers.

“Patients with infections due to carbapenem-resistant pathogens, including CRE, have significantly worse outcomes, including higher mortality rates, than those with infections due to susceptible pathogens. Current approaches to infection control and prevention have not been adequate to prevent spread,” said Tim Henkel, M.D., Ph.D., Chief Medical Officer at VenatoRx. “Based upon our pre-clinical and Phase 1 trial results, we believe that VNRX-5133, in combination with cefepime, has the potential to provide a valuable broad-spectrum treatment option to meet unmet medical needs for patients. We are optimistic about the potential this BL/BLI combination has to serve as a therapy for patients affected by these difficult-to-treat infections.”

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About VenatoRx Pharmaceuticals, Inc.
VenatoRx is a private pharmaceutical company that is focused on the discovery and development of novel anti-infectives to treat multi-drug-resistant bacterial infections and hard-to-treat viral infections. Founded in 2010, VenatoRx has built a world-class in-house R&D organization that has filed over 100 patents spanning multiple research programs. VenatoRx has received significant funding awards from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH); Wellcome Trust; the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Service (HHS); the U.S. Department of Defense’s Defense Threat Reduction Agency (DTRA); and CARB-X, and as well as private equity investments from Versant Ventures, Abingworth and Foresite Capital. For more information, please visit www.venatorx.com.

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