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Venatorx Pharmaceuticals Announces Positive Phase 1 Results for VNRX-7145

Investigational oral beta-lactamase inhibitor VNRX-7145 was well-tolerated with no safety signals up to the highest dose as a single agent

Ceftibuten/VNRX-7145 Combination Phase 1 Study Initiated with Top Line Results Expected Fourth Quarter 2021

Company Plans to Initiate Phase 3 Clinical Trial for Ceftibuten/VNRX-7145 in Second Half 2022

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MALVERN, Pa.--(BUSINESS WIRE)--Venatorx Pharmaceuticals today announced positive top line results for its Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial (ClinicalTrials.gov – NCT04243863) of VNRX-7145, a novel component of the investigational oral antibiotic combination product. VNRX-7145, in combination with ceftibuten, a third-generation, orally-bioavailable cephalosporin antibiotic, is designed for the treatment of patients with infections caused by multi-drug resistant (MDR) gram-negative pathogens that are resistant to current standard-of-care oral and intravenous antibiotics, including fluoroquinolones, cephalosporins and carbapenems.

The Phase 1 study was a 2-part, first-in-human dose-ranging study to evaluate the safety and pharmacokinetics (PK) of escalating oral doses of VNRX-7145. In part 1, subjects received single ascending doses of VNRX-7145; in part 2, subjects received multiple escalating doses of VNRX-7145 for 10 days. There were no serious adverse events, and VNRX-7145 was well-tolerated up to the highest single or multiple doses administered. VNRX-7145 had excellent oral bioavailability, dose-proportional PK across the doses studied, and readily achieved efficacy exposure targets identified in non-clinical studies. Complete results from this study will be presented at an upcoming scientific meeting.

With these positive topline results in hand, Venatorx is continuing the development of VNRX-7145 with a Phase 1 drug-drug interaction (DDI) study (ClinicalTrials.gov – NCT04877379), which will provide an initial assessment of the safety and PK of single and multiple doses of VNRX-7145 and ceftibuten, the selected beta-lactam partner, when co-administered. Top line results are expected in the fourth quarter 2021.

“There is an urgent need for oral antibiotics to combat resistant gram-negative pathogens. Currently, there are no approved orally-bioavailable beta-lactam or beta-lactam/beta-lactamase inhibitor combinations that cover Enterobacterales expressing key class A or D carbapenemases or class C cephalosporinases,” said Christopher J. Burns, Ph.D., President and CEO of Venatorx. “The increasing rate of infections caused by these organisms, and the resulting need for hospitalization for intravenous therapy, places a high toll on patient health and creates significant public health and economic burdens.”

“Based on the initial human safety and PK data and the potent *in vitro* activity against MDR Enterobacterales, we believe that the combination of VNRX-7145 with ceftibuten represents a high-potential treatment option to address the needs of patients with infections caused by ESBL-producing organisms including the possibility of reducing hospitalizations,” said Tim Henkel, M.D., Ph.D., Chief Medical Officer at Venatorx. “We thank the investigators and subjects who have participated, and will participate, in this and future studies, as well as the National Institute of Allergy and Infectious Diseases, for their support. As we continue to progress our program through Phase 1, we look forward to meeting with the FDA to finalize the protocols for our Phase 3 clinical trial, which we expect to initiate in the second half of 2022.”

About VNRX-7145

VNRX-7145 is the orally bioavailable etzadroxil prodrug of VNRX-5236, a broad-spectrum boronic acid beta-lactamase inhibitor (BLI). VNRX-7145 is being developed in combination with ceftibuten, a third-generation, orally-bioavailable cephalosporin antibiotic. *In vitro* and *in vivo* studies demonstrated that VNRX-5236 restored the activity of ceftibuten against strains of Enterobacterales expressing extended spectrum beta-lactamases (ESBLs) and serine carbapenemases. The spectrum of inhibition includes Ambler class A ESBLs, class C cephalosporinases, and class A and D carbapenemases (KPC and OXA-48, respectively).

VNRX-7145 alone and in combination with ceftibuten is an investigational drug and is not approved in any country for clinical use. For more information about VNRX-7145, including open access to published posters and manuscripts, please visit: www.venatorx.com/publications.

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About Venatorx Pharmaceuticals, Inc.

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, Venatorx is in Phase 1 with its first antiviral compound (VNRX-9945), a Hepatitis B virus inhibitor. The Company is also developing 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, its partners, investors and pipeline development, 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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