Venatorx Pharmaceuticals and GARDP Partner to Develop New Antibiotic for Hospital Acquired Infections with Limited Treatment Options

Serious bacterial infections among major causes of disability and death for people in healthcare settings.

Collaboration comes at critical time with study showing bacterial infections present in half of deceased COVID-19 patients.

Malvern, PA and Geneva, Switzerland, April 29, 2020 – Venatorx Pharmaceuticals and the Global Antibiotic Research and Development Partnership (GARDP) today announced a collaboration to accelerate the development of, and access to, cefepime-taniborbactam (formerly cefepime/VNRX-5133). Cefepime-taniborbactam is an investigational combination of the fourth-generation antibiotic cefepime with taniborbactam, a novel, broad-spectrum beta-lactamase inhibitor that restores the activity of cefepime against carbapenem-resistant Enterobacterales (CRE) and carbapenem-resistant *Pseudomonas aeruginosa* (CRPA).

GARDP will collaborate with Venatorx to complete the development of cefepime-taniborbactam, which includes a phase 3 complicated urinary tract infection (cUTI) trial, which is already in progress; additional clinical trials in adults with multidrug-resistant infections; and clinical development activities and trials 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.

The World Health Organization has identified CRE and CRPA as 'critical-level' pathogens posing the greatest threat to global health and urgently requiring new antibiotics. These pathogens are most common in healthcare settings and are among the major causes of disability and death in these places. Bacteria can enter the body through wounds and surgery sites, ventilators and catheters, potentially leading to lung, urinary tract, abdominal and bloodstream infections.

In Europe, hospital infections are responsible for 37,000 attributable deaths annually, whereas in the United States, 98,000 deaths are attributed to hospital infections annually. While there are limited surveillance systems in low- and middle-income countries, indicators point to a higher burden of hospital infections.

Many of the pathogens responsible for these infections have become increasingly resistant to first-line antibiotics and are often treated with the carbapenem class of

antibiotics, usually reserved for the most serious infections including multidrug-resistant infections. However, since the introduction of this class of antibiotics in the 1980s, pathogens have progressively developed carbapenem-resistance.

“Antibiotic resistance presents a growing public threat and is exacerbated by global pandemics such as COVID-19,” said Christopher J. Burns, Ph.D., President and CEO of Venatorx Pharmaceuticals. “A recent study published in The Lancet showed that 98% of hospitalized COVID-19 patients received concomitant antibiotic therapy and that 50% of those who died also had secondary bacterial infections. The need for effective, broad spectrum antibiotics – both intravenous and oral – is critical, now more than ever. Our partnership with GARDP comes at a vital time to safeguard our ability to advance cefepime-taniborbactam through phase 3 clinical trials and afford access to patients, including children, who are more susceptible to hard-to-treat bacterial infections.”

“More than a hundred thousand people die every year in high-income countries due to hospital infections and indicators point to a significantly higher burden in low- and middle-income countries,” said Dr. Manica Balasegaram, Executive Director of GARDP. “Our collaboration with Venatorx enables us to accelerate the development of a critically needed treatment for antibiotic-resistant infections in adults and children. Significantly, we are committed to working together to ensure this treatment is available to everyone who needs it, wherever they live. Just like COVID-19, antibiotic resistance is a health security crisis that moves silently and doesn’t stop at national borders. No single country, company or organization can fight drug resistance alone. It can only be done in partnership.”

About Cefepime-Taniborbactam

Taniborbactam, formerly known as VNRX-5133, is the only known beta-lactamase inhibitor (BLI) in advanced clinical development that inhibits both serine- and metallo-beta-lactamases. When combined with cefepime, a fourth generation cephalosporin antibiotic, taniborbactam drives antimicrobial activity against gram-negative bacteria including carbapenem-resistant Enterobacterales (CRE) and carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) that have acquired multi-drug resistance (MDR) to aminoglycosides, quinolones and beta-lactams via classes A, B, C and D beta-lactamase (BL) expression. This includes pathogens that produce extended-spectrum beta-lactamases (ESBLs), AmpC beta-lactamases, and/or co-produce ESBLs and AmpC, KPC, OXA, NDM, and VIM. Sponsored by Venatorx Pharmaceuticals, cefepime taniborbactam has the potential to offer broad-spectrum antibacterial activity that is favorable over currently available therapies, especially in high-risk patients where a delay in effective treatment may lead to suboptimal clinical outcomes.

Venatorx is currently enrolling a Phase 3 clinical trial of cefepime-taniborbactam in patients with complicated urinary tract infections (cUTIs). This project has been funded in whole or 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 No. HHSN272201300019C, The Wellcome Trust under Award No.

360G-Wellcome-101999/Z/13/Z, and the Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services under Contract No. HHSO100201900007C.

About Venatorx Pharmaceuticals

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 research and discovery 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. www.venatorx.com

About GARDP

The Global Antibiotic Research and Development Partnership (GARDP) is a not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. Established by the World Health Organization (WHO) and the Drugs for Neglected Disease *initiative* (DNDi) in 2016, GARDP is a core element of WHO's Global Action Plan on Antimicrobial Resistance. We were created to ensure that everyone who needs antibiotics receives effective and affordable treatment, no matter where they live. We aim to develop five new treatments by 2025 to fight drug-resistant infections, focusing on sexually transmitted infections, sepsis in newborns and infections in hospitalized adults and children. GARDP is funded by the governments of Germany, Luxembourg, Monaco, Netherlands, South Africa, Switzerland, United Kingdom, as well as Médecins Sans Frontières and private foundations. www.gardp.org