

Novel antibiotic treatment to become the first in the GARDP portfolio to be reviewed by US FDA for potential approval

Geneva, 15 August 2023 – A new antibiotic treatment is [now on track](#) to receive final review by the US Food & Drug Administration (FDA). If approved it would represent a significant advance in the treatment of patients with complicated urinary tract infections (cUTI), and potentially those with serious infections caused by highly resistant bacteria. The FDA's decision to accept for review the New Drug Application (NDA) for cefepime-taniborbactam, developed by Venatorx Pharmaceuticals, Inc. (Venatorx) in partnership with the Global Antibiotic Research & Development Partnership (GARDP), means that approval for this new combination drug could come as early as 22 February 2024.

If successful, cefepime-taniborbactam would become the first new treatment in GARDP's clinical development portfolio to be approved and marks an important milestone in terms of global equitable access to new antibiotic treatments. GARDP, which supported the pivotal phase 3 trial, has exclusive rights to distribute and sub-distribute cefepime-taniborbactam, once it is approved for clinical use, in 64 low- and lower middle-income countries, as well as the public markets in India and South Africa.

“With cefepime-taniborbactam now on track to become the first new antibiotic treatment in our portfolio to gain regulatory approval, we are one significant step closer to achieving our ambition of delivering five new treatments by 2025,” said Seamus O'Brien, R&D Director of GARDP. “We are proud to have supported Venatorx on this project that may offer a new treatment option for people with drug-resistant infections around the world.”

The cefepime-taniborbactam NDA is supported by positive efficacy and safety results of a phase 3 trial in patients with complicated urinary tract infections, including acute pyelonephritis (i.e. kidney infections).

“This milestone represents the culmination of unwavering dedication, scientific excellence, and the collaborative efforts of our talented team, partners, and clinical investigators,” said Christopher J. Burns, Ph.D., Chief Executive Officer of Venatorx. “We are grateful to GARDP for their essential support, and we look forward to continuing to work together to address the challenges posed by antimicrobial resistance for the benefit of global public health.”

In addition to supporting the phase 3 trial, GARDP is leading the efforts to accelerate the approval of cefepime-taniborbactam for children and newborns. The approval of new medicines for use in paediatric populations, including antibiotics, typically lags behind the approval for adults by nearly a decade. GARDP has taken the initial preparatory steps with the hope of accelerating the process.

GARDP has recently launched an [observational study](#) to better understand the current management and clinical outcomes for patients with carbapenem-resistant infections in South African and Indian hospitals. The results of this study will inform the design of future interventional trials and determine the appropriate clinical sites to carry out studies with cefepime-taniborbactam and other novel antibiotics as potential treatments for infections caused by World Health Organization [priority pathogens](#).

About GARDP

The Global Antibiotic Research and Development Partnership (GARDP) is a Swiss not-for-profit organization developing new treatments for drug-resistant infections that pose the greatest threat to health. GARDP was created by the World Health Organization (WHO) and the Drugs for Neglected Diseases initiative (DNDi) in 2016 and legally founded in 2018 to ensure that everyone who needs antibiotics receives effective and affordable treatment. GARDP is funded by the governments of Australia, Germany, Japan, Monaco, the Netherlands, the Public Health Agency of Canada, South Africa, Switzerland, the United Kingdom, the Canton of Geneva, as well as the European Union, Wellcome Trust and private foundations. GARDP is registered under the legal name GARDP Foundation. www.gardp.org

About Venatorx Pharmaceuticals, Inc.

Venatorx is a private, pre-commercial pharmaceutical company focused on improving health outcomes for patients with difficult-to-treat drug-resistant gram-negative bacterial infections and viral infections. Venatorx's lead asset, cefepime-taniborbactam, is an investigational antibiotic that completed a phase 3 study ([NCT03840148](#)) in adults with complicated urinary tract infections (cUTI), including pyelonephritis and is under FDA review with a PDUFA action date of February 22, 2024. Development of cefepime-taniborbactam 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 Wellcome Trust under award number 360G-Wellcome-101999/Z/13/Z, and continues with federal funds from the Biomedical Advanced Research and Development Authority, Administration for Strategic Preparedness and Response, Department of Health and Human Services 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 People's Republic of China, Macau, Hong Kong, Taiwan, South Korea, and select countries in Southeast Asia (the "Territory"). In April 2020, [Venatorx and GARDP announced a collaboration](#) to accelerate the development of, and access to, cefepime-taniborbactam for adult and pediatric populations in certain regions, including many low- and lower-middle-income countries. For more information about Venatorx and its anti-infectives portfolio, please visit www.venatorx.com.