Venatorx Pharmaceuticals and Menarini Group Enter Commercial Agreement for Cefepime-Taniborbactam in 96 Countries

Malvern, PA, and Florence, Italy, January 9th, 2024 – Venatorx Pharmaceuticals, a private, pre-commercial pharmaceutical company focused on improving health outcomes for patients with multidrug-resistant bacterial infections and hard-to-treat viral infections, and Menarini Group, an Italian biopharmaceutical group, today announced that they have entered into an agreement under which Menarini will acquire the exclusive rights to commercialize, upon approval of relevant health authorities, cefepime-taniborbactam in 96 countries in Europe, Latin America, Middle East, Turkey and North Africa and the Commonwealth of Independent States (CIS). Under the terms of the agreement, Venatorx will receive an upfront licensing fee, additional R&D, regulatory, and sales-based milestone payments, and potential royalty payments based on a percentage of net sales.

“With its global commercial infrastructure and significant experience in commercializing infectious disease products, including antibiotics, Menarini is ideally positioned to bring cefepime-taniborbactam to key geographic markets,” said Christopher J. Burns, Ph.D., Chief Executive Officer of Venatorx. “Development of novel antibiotics with comprehensive resistance coverage is necessary to address critical global unmet medical needs and provide hope for patients and healthcare providers alike to effectively treat the rapidly growing number of drug-resistant gram-negative infections.”

“At Menarini, we believe that the addition of cefepime-taniborbactam expands our existing AMR anti infectives portfolio and provides the opportunity to further strengthen our building of an important antibiotics portfolio focused on the critical pathogens responsible for the vast majority of antibiotic resistance” said Elcin Barker Ergun, CEO of the Menarini Group. “By leveraging our expertise and Menarini’s expansive commercial infrastructure, we will provide the resources needed to optimize the commercialization, upon approval of relevant health authorities, of cefepime-taniborbactam and ensure patient access to this medicine across our global footprint.”

About Cefepime-Taniborbactam
Cefepime-taniborbactam is an investigational intravenous (IV) beta-lactam/beta-lactamase inhibitor (BL/BLI) antibiotic combination being developed for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP). A New Drug Application for cefepime-taniborbactam was accepted for review by the US FDA for cUTI, including pyelonephritis with a PDUFA date of February 22, 2024.

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) that, in combination with cefepime, is being studied as a potential treatment option for patients with serious bacterial infections caused by antibiotic resistant gram-negative bacteria, most notably Extended Spectrum Beta-lactamase (ESBL)-expressing Enterobacterales, Carbapenem-Resistant Enterobacterales (CRE), and Multidrug-resistant (MDR) *Pseudomonas aeruginosa* (MDR-PA), which can include Carbapenem-Resistant *P. aeruginosa* (CRPA).

Cefepime-taniborbactam has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the U.S. Food and Drug Administration (FDA) for the treatment of cUTI and HABP/VABP.

Funding Partners and Collaborators
Development of cefepime-taniborbactam began with federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. 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 (BARDA), Administration for Strategic Preparedness and Response, Department of Health and Human Services under contract numbers HHSO100201900007C and 75A50122C00080.

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. Venatorx has granted GARDP exclusive rights to distribute and sub-distribute cefepime-taniborbactam, once it is approved for clinical use, in certain low- and lower middle-income countries.

In November 2023, Venatorx entered into an exclusive license agreement with Melinta Therapeutics to commercialize cefepime-taniborbactam in the U.S.

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 has completed a Phase 3 study (NCT03840148) in adults with complicated urinary tract infections (cUTI), including pyelonephritis and an NDA is under FDA review with a PDUFA action date of February 22, 2024. In October 2022, BARDA awarded a Project Bioshield contract of up to $318 million to Venatorx for development and procurement of cefepime-taniborbactam for the treatment of resistant Gram negative infections, including melioidosis. As part of its broader pipeline, Venatorx is also developing an oral BL/BLI antibacterial, ceftibuten-ledaborbactam etzadroxil, that will advance directly to a global Phase 3 cUTI clinical trial under a recently announced new BARDA contract. For more information about Venatorx and its anti-infectives portfolio, please visit www.venatorx.com.

About Menarini Group
The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over $4.4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.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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