VenatoRx Pharmaceuticals Receives FDA's QIDP and Fast Track Designations for Development of Its Lead Antibiotic Program

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MALVERN, Pa.--(BUSINESS WIRE)--VenatoRx Pharmaceuticals, a private clinical-stage pharmaceutical company, announced today that the FDA has granted the company's lead antibiotic program, VNRX-5133, an injectable broad-spectrum β-lactamase inhibitor combined with a marketed β-lactam antibiotic, both the Qualified Infectious Disease Product (QIDP) and Fast Track designations. The designations were granted for both complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI).

VNRX-5133 is a novel β-lactamase inhibitor with potent and selective direct inhibitory activity against both serine- and metallo-β-lactamases (i.e., Ambler Classes A, B, C, and D). VNRX-5133, in combination with a marketed β-lactam antibiotic, has the potential to address the serious unmet medical need for a safe and effective therapy for treatment of infections caused by multi-drug resistant (MDR) gram-negative bacteria, particularly carbapenem-resistant Enterobacteriaceae (CRE) and multi-drug resistant *Pseudomonas aeruginosa*.

"The steady increase in β-lactamase-mediated resistance in gram-negative pathogens threatens the clinical utility of all β-lactam antibiotics, a critically important class of drugs. We believe this program has the potential to be a part of the solution to that problem," said Tim Henkel, MD, PhD, Chief Medical Officer of VenatoRx. "It is gratifying to receive the FDA's validation of our drug's potential. The regulatory opportunities created by these designations should expedite its development," said Jennifer Grodberg, PhD, RAC, VenatoRx's Vice President of Regulatory Affairs. "We look forward to increased interactions with the Agency as this development program proceeds."

The QIDP designation was created by the Generating Antibiotic Incentives Now (GAIN) Act, which was part of the FDA Safety and Innovation Act of 2012 (FDASIA) and provides certain incentives for the development of new antibiotics, including priority review and an additional five years of market exclusivity.

The Fast Track designation facilitates the development of drugs with the potential to fulfill an unmet medical need by enabling more frequent interactions with the FDA and expedited review, leading to faster approval and earlier market access for patients. VNRX-5133 is currently in Phase 1 clinical development. VenatoRx plans to start pivotal registration clinical trials in 2018.

The VNRX-5133 program 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 and the Wellcome Trust.

About VenatoRx Pharmaceuticals, Inc.

VenatoRx Pharmaceuticals is a private pharmaceutical company founded in 2010 dedicated to the discovery and development of novel agents to address the threat of antibiotic bacterial resistance. Its lead clinical program combines VNRX-5133, a novel, broad-spectrum β-lactamase inhibitor, with a marketed β-lactam antibiotic. For more information, please visit www.venatorx.com.

Forward-Looking Statements

This press release contains "forward-looking statements" concerning the development of the company's products, the potential benefits and attributes of such products, and the company's expectations regarding its prospects. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. VenatoRx undertakes no obligation to update any forward-looking statements for any reason.

Contacts

VenatoRx Pharmaceuticals
Christopher Burns, Ph.D.
President and Chief Executive Officer
610-644-8935
IR@venatorx.com