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Venatorx Pharmaceuticals Announces First Patient Dosed in Phase 1 Study of VNRX-9945 for the Treatment of Chronic Hepatitis B Virus Infection

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MALVERN, Pa.--(BUSINESS WIRE)--Venatorx Pharmaceuticals today announced that the first patient was dosed in a Phase 1 clinical trial evaluating VNRX-9945, a highly potent, broadly active viral replication inhibitor for the treatment of chronic hepatitis B virus (HBV) infection.

VNRX-9945 is a third-generation, orally bioavailable core protein allosteric modulator (CpAM). CpAMs represent an attractive class of direct-acting antivirals that block the formation of new virus particles and cccDNA *in vitro.*[1] In preclinical studies, VNRX-9945 demonstrated broad antiviral activity against multiple HBV genotypes *in vitro* and suppressed HBV DNA to below the lower limit of quantitation in an animal model of HBV infection.

The Phase 1 clinical trial will evaluate the safety and pharmacokinetics of single and multiple ascending doses of VNRX-9945, administered orally in healthy adult volunteers (ClinicalTrials.gov – NCT04845321).

“The need for a true cure for HBV is clear. Current front-line therapies only partially suppress HBV replication, are not curative and require therapy for an indefinite duration, adding to patient burden,” said Christopher J. Burns, Ph.D., President and CEO of Venatorx. “Novel inhibitors of HBV are required to further suppress viral replication and provide the conditions required to achieve immune control, termed a ‘functional cure’. We are excited to advance VNRX-9945 to the clinic as a promising HBV drug candidate. We believe combination regimens that include VNRX-9945 have the potential to lead to said functional cure in chronic HBV patients.”

About Hepatitis B Virus

There are more than 250 million individuals chronically infected with chronic HBV worldwide who are at risk from complications due to liver disease and liver cancer. Chronic HBV infection is currently managed with nucleos(t)ide reverse transcriptase inhibitors (NrtIs) or pegylated-interferons that suppress HBV DNA replication and normalize alanine aminotransferase (ALT) levels, leading to reductions in morbidity and mortality. Unfortunately, these agents are not curative and patients generally exhibit poor off-treatment responses that require indefinite therapy.

About Venatorx Pharmaceuticals

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.

References

[1.] Berke, J.M. et al. Capsid assembly modulators have a dual mechanism of action in primary human hepatocytes infected with hepatitis B virus. *Antimicrobial Agents and Chemotherapy 2017, 61: e00560-17.*

Contacts

Heather Hunter
Vice President, Communications
hunter(at)venatorx(dot)com
484.329.8327