

Virion Therapeutics Provides Update on its VRON-0200 Clinical Development Program for HBV Functional Cure on World Hepatitis Day 2025

PHILADELPHIA, PA, UNITED STATES, July 28, 2025 /EINPresswire.com/ -- Virion Therapeutics, LLC, a clinical-stage biotechnology company, developing novel T cell-based immunotherapies that utilize first-in-class checkpoint modifiers, today, on World Hepatitis Day, provided a corporate update highlighting continued progress across its functional cure program for chronic hepatitis B virus (CHB).



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Dr. Sue Currie, COO, Virion

KEY PROGRAM HIGHLIGHTS

- o VRON-0200's Phase 1b program is fully enrolled, with 34 CHB patients now treated with VRON-0200, including a combination cohort with investigational antivirals; longer term clinical data from the full cohort is expected in Q4 2025
- o VRON-0200 clinical data, presented earlier this year at APASL and EASL demonstrated:
- VRON-0200 was safe and well tolerated, with no serious

treatment-related adverse events (SAEs), treatment discontinuations, or treatment-related clinical laboratory abnormalities reported

- HBsAg declines were observed in patients treated with an intramuscular (IM) injection of VRON-0200 even though VRON-0200 does NOT directly target S-antigen, suggesting a possible broadening, and restoration of anti-HBV immune responses
- After a single VRON-0200 prime dose, rapid and profound HBsAg declines were observed in all evaluable patients 7 days after the first combination dose. These types of responses have not been previously reported, even with PEG-IFN containing regimens
- These data suggest VRON-0200 could be the key backbone agent in future HBV functional cure regimens
- o The Phase 1b study is ongoing these data, from all Cohorts, as well as the long-term followup and exploratory analyses, will further inform future treatment strategies to maximize functional cure rates and potentially expand patient populations
- o A global Phase 2b study ("SPARK-B") for HBV Functional Cure is in development; in parallel,

additional manufacturing activities to support late-stage development are ongoing o Virion is in partnership discussions to further accelerate development and maximize access to a potential functional cure for persons living with CHB worldwide

"Despite a preventative HBV vaccine, CHB remains a widespread global problem affecting 254 million persons and contributing to 1.1 million deaths/year from liver related complications. On this World Hepatitis Day, Virion, along with its partners, are committed to finding a cure for CHB," said Dr. Andrew D. Luber, CEO of Virion. Luber added, "It is exciting to see the VRON-0200 Phase 1b data support our "Spark and Fan" treatment model, with VRON-0200 "sparking" a new HBV-specific immune response, and then the "fanning" of this response with the addition of antivirals, which remove the virus and it's immunosuppressive effects."

Dr. Sue Currie, Virion's COO commented, "This "Spark and Fan" treatment strategy could potentially offer a simple and well tolerated solution for a wide range of future HBV functional cure regimens for patients worldwide. We are excited to continue our current VRON-0200 clinical development program, including the planning of our future SPARK-B Phase 2b clinical trial. On this World Hepatitis Day, we are aware of the burden of CHB, and the urgent unmet medical need to achieve a functional cure that is safe, convenient, effective, and accessible for persons worldwide. What makes VRON-0200 so promising, besides being the first new immune modulator to restore broad anti-HBV immunity since pegylated-interferon, is its ease of dosing (a single i.m. injection), and favorable safety and tolerability profile, all critical factors to future functional cure treatments for persons with CHB."

ABOUT CHRONIC HEPATITIS B

Despite a preventative vaccine, cases of chronic hepatitis B (HBV) continue to rise, with an estimated 254 million persons infected worldwide and 1.1 million deaths per year from HBV-related liver complications. Chronic HBV remains a global health issue with a high unmet medical need since there is no cure available. The current standard of care requires lifelong antiviral therapy to maintain control of the virus.

To learn more about hepatitis and World Hepatitis Day, visit: www.worldhepatitis.org

ABOUT VRON-0200

VRON-0200 is a therapeutic immunotherapy, administered by intramuscular injection, designed with the goal of providing a functional cure for chronic HBV infection. While the virus itself stimulates HBV-specific CD8+ T cells, for those patients that can't clear the initial infection, their T cells soon become exhausted, placing limits on their ability to proliferate and control the virus. An ongoing Phase 1b trial has shown VRON-0200 to be safe, well tolerated, immunogenic, and has anti-HBV activity in chronically HBV-infected patients on nucleos(t)ide therapy. More details of the study can be found at ClinicalTrials.gov (Identifier: NCT06070051).

ABOUT VIRION THERAPEUTICS (VIRION)

Virion Therapeutics, LLC is a clinical-stage company developing novel T cell-based

immunotherapies to cure cancer and chronic infectious diseases that utilize proprietary genetically encoded checkpoint modifiers to enhance and broaden CD8+ T cell responses to a tumor or chronic infection. Virion has since developed a robust pipeline, including its lead VRON-0200 clinical program, and several additional IND-enabling programs, such as its VRON-0300 oncology program for advanced solid tumors, leveraging its proprietary platform technologies.

To learn more, visit <u>www.VirionTx.com</u>

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