Virion Therapeutics Reports New Data from Two Clinical Presentations at EASL 2025, including Rapid and Profound Hepatitis B Surface Antigen Declines with the First VRON-0200 Containing Combination Therapy for HBV Functional Cure

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Highlights from the Data Presentations

> This novel and exciting approach.....may represent a paradigm shift in treatment approaches that could bring new therapies that include VRON-0200 to produce meaningful Functional Cure rates."
>
> *Professor Ed Gane, M.D.*

• Over 8,295 and 821 safety days reported in VRON-0200 alone (n=27), and VRON-0200 combination treated patients (n=7), respectively; VRON-0200 was well tolerated, with no serious treatment-related adverse events (SAEs), treatment discontinuations, or treatment-related clinical laboratory abnormalities reported

• HBsAg declines were observed in 27% of patients treated with VRON-0200, through Day 154, 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 (n=6; range: -3.6 to -1.3 log10IU/mL) with the addition of an investigational small interfering RNA plus monoclonal antibody regimen 28 days later - these declines were observed one week after the first combination dose, and continued to decrease with additional monthly dosing through Week 20 (range: -3.8 to -2.2 log10IU/mL); two patients achieved complete HBsAg loss, one within 7 days of the first combination dose

• These types of responses have not been previously reported, even with PEG-IFN containing regimens, and have the potential to alter the HBV Functional Cure treatment landscape with

VRON-0200 being a key component backbone agent in future combination treatments

Virion Therapeutics, LLC, a clinical-stage biotechnology company, developing novel T cell-based immunotherapies, reported data from two clinical presentations at EASL, including rapid and profound anti-HBV responses, and favorable safety and tolerability results, from the first-ever combination therapy with VRON-0200, its novel, first-in-class, checkpoint modifier immunotherapy, for HBV functional cure, presented by Professor Ed Gane, M.D., from the University of Auckland, as a late breaker at the EASL Congress 2025 (The European Association for the Study of the Liver) in Amsterdam, The Netherlands.

These Phase 1b data, in 34 chronically infected hepatitis B patients, on nucleos(t)ide antiviral therapy, comprised of 3 cohorts who received a single Prime, or Prime and Boost intramuscular (i.m.) injection of VRON-0200 (n=27) (Cohorts 1 and 2), or a single i.m. VRON-0200 prime injection, followed by monthly doses of elebsiran (a small interfering RNA) plus tobevibart (a monoclonal antibody against HBsAg) starting on day 28 (n=7), and then monthly for 6 total doses (Cohort 3). All Cohorts demonstrated that VRON-0200 alone, or in combination with other agents, was safe and well-tolerated, with no significant treatment-related adverse events reported and no treatment-related clinical laboratory abnormalities, including liver function tests. In 26 patients treated with VRON-0200 only (Cohorts 1 and 2), with at least 154 days of follow up, declines in HBV surface antigen (HBsAg) ranging from -2.3 to -0.4 log10 IU/mL were observed in 7 patients (27%). In those patients who received the VRON-0200 combination therapy (Cohort 3), rapid and profound HBsAg declines were observed in all evaluable patients (n=6) within 7 days of the first combination dose being added (range: -3.6 to -1.3 log10IU/mL); these responses continued to decline with additional monthly doses out to Week 20. Two patients achieved total HBsAg loss (one at Day 35 (7 days post the first combination dose) and the other at Day 140); all patients had HBsAg levels <10 IU/mL by Day 35, and all patients seroconverted from HBsAb negative to positive.

Professor Ed Gane, M.D., from the University of Auckland, and one of the study investigators, commented: “A barrier to HBV Functional Cure has been the inability to stimulate immune responses in this patient population with highly limited pre-existing immunity. VRON-0200 is unique in that it can restore HBV immunity, even following a single i.m. dose; and now, these results show those VRON-0200 responses can be rapidly and substantially enhanced with the addition of antiviral agents that inhibit the virus. This novel and exciting approach, where a patient’s immune response is “sparked” with VRON-0200, and then “fanned” by the removal of the HBV virus, and its immunosuppressive effects, with antiviral agents, may represent a paradigm shift in treatment approaches that could bring new therapies that include VRON-0200 to produce meaningful Functional Cure rates.”

“These new VRON-0200 clinical study data highlight its potential as a key component in future HBV Functional Cure regimens,” said Dr. Sue Currie, COO of Virion, and one of the study authors. “The improved and rapid HBsAg declines observed following a single prime VRON-0200 dose,

plus the addition of antiviral agents, have not been previously reported, even with pegylated-interferon combination regimens. We are now exploring VRON-0200 in combination with other agents and classes and believe its convenience, tolerability, and enhanced and rapid anti-HBV activity, could result in shorter treatment durations, and nicely positions it not only as a possible replacement for pegylated-interferon, but as a potential backbone to a cure for chronic HBV worldwide. We look forward to presenting additional data from this study later this year."

Professor Grace Wong, M.D., from the Chinese University of Hong Kong, and one of the study investigators commented: "Treatment options for patients with Chronic HBV are very limited and often require up to a year, or sometimes longer, of treatment, with high rates of adverse events, and low rates of functional cure. These data demonstrate the potential to have a simple, well tolerated immune-modulator, that could be combined with other agents to potentially shorten the time of treatment and also improve the overall response rates. I look forward to seeing the ongoing data from this study."

Summary of VRON-0200 Phase 1b clinical trial design
VRON-0200 is a Phase 1b, multi-center, open-label, dose escalation, prime only, and prime plus boost, therapeutic immunotherapy study to evaluate the safety, tolerability, immunology, and other clinical measures:

- Inclusion criteria: Non-cirrhotic, HBeAg positive or negative, chronic hepatitis B patients currently taking nucleos(t)ide antiviral therapy with HBV DNA < 40 IU/mL and HBsAg < 500 IU/mL (< 1,000 IU/mL for Cohort 3)
- Dose escalation: Cohort 1 (low dose) (ENROLLED); Cohort 2 (high dose) (ENROLLED)
- Prime or Prime-Boost: In each cohort, patients are randomized to receive either a prime dose only or a prime and boost regimen
- Cohort 3: Patients are randomized to receive VRON-0200 prime plus 6 monthly subcutaneous doses of elebsiran and tobevibart starting on Day 28, alone, or with a VRON-0200 boost at Day 196 (ENROLLED)

More details of the study can be found at ClinicalTrials.gov (Identifier: NCT06070051).

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.

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. Preclinical data support the hypothesis that VRON-0200, through checkpoint modification, can amplify, broaden, and enhance T cell responses that may include T cells that are not normally activated during a chronic HBV infection, which results in improved viral control. 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.

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 www.VirionTx.com

Dr. Sue Currie, PhD
Virion Therapeutics, LLC
scurrie@viriontx.com
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