

AstriVax Therapeutics Initiates Clinical Development of AVX70371, a Hepatitis B immunotherapy using Launch-iT technology

- Third asset to advance into clinical trials, validating broad potential of Launch-iT platform
- All subjects treated with first dose of AVX70371 Launch-iT, as part of multiple dosing schedule
- Potential first-in-class treatment that could form part of functional cure for over 250 million patients suffering from chronic hepatitis B virus (HBV) infection

Leuven, Belgium, June 5, 2025 – <u>AstriVax Therapeutics NV</u>, a clinical stage immunotherapy company developing novel treatments for chronic infections based on its proprietary Launch-iT technology, announced today the start of clinical development with AVX70371 for chronic hepatitis B virus (HBV) infection.

The phase I RUBY study (NCT06989788) will evaluate the safety, tolerability and immunogenicity of repeated injections of AVX70371 in 16 healthy adult volunteers at the Centre for Vaccinology of the Ghent University, Belgium. Up to three doses of AVX70371 are being evaluated in preparation for an assessment in a chronic HBV patient population, who are known to experience HBV-specific immune exhaustion. All subjects have now been treated with the first dose of AVX70371. The trial is expected to be completed in the second half of 2026, with an interim analysis before the end of 2025.

"AVX70371 has been designed to elicit a specific T-cell immune response against infected hepatocytes in which HBV is actively replicating. Knowing that patients with chronic hepatitis B suffer from immune exhaustion, this targeted immunotherapy approach is expected to intervene at the source of the chronic viral infection," **said Mathieu Peeters, M.D., Chief Development Officer** at AstriVax Therapeutics. "Starting clinical development with AVX70371 is the first step in the development of a new approach that could form the basis of a functional cure for chronic HBV infection."

"Following positive results from our first clinical study in 2024, which evaluated the safety and immunogenicity of our Launch-iT technology platform, starting the clinical development with our first therapeutic Launch-iT program is a significant milestone for AstriVax Therapeutics. Despite available preventive vaccines, chronic hepatitis B still affects over 250 million people worldwide, so there is an ongoing need for improved



options for patients beyond life-long antiviral treatment," **Hanne Callewaert, Ph.D., cofounder and CEO** of AstriVax Therapeutics, added. "AstriVax Therapeutics is also in the process of selecting a second immunotherapy Launch-iT clinical candidate for treating human papilloma virus (HPV) infection. Our plan is to rapidly advance this program towards clinical development in patients, further supporting our track record of moving assets quickly into the clinical validation phase."

About Launch-iT

Launch-iT (launched Immnunotherapy) is a plasmid-based technology that can rapidly generate viral vectors encoding novel antigens of interest as immunotherapy drug candidates. The tolerability and effectiveness of the platform has been validated in the SAFYR clinical study, which demonstrated that a single injection with AVX70120 (Yellow fever) or AVX70481 (Rabies) is very well tolerated and can induce high and long-lasting antibody titers and T-cell counts including CD4 and CD8 T-cells.

About AstriVax Therapeutics

AstriVax Therapeutics is a clinical stage biopharmaceutical company developing novel immunotherapies that could offer broad and long-lasting treatment of chronic infectious diseases. Leveraging its proprietary Launch-iT plug and play plasmid-based technology, AstriVax Therapeutics is building a portfolio of product candidates targeting chronic viral infections, initially focused on hepatitis B virus (HBV) and human papilloma virus (HPV) infections. The company's Launch-iT product candidates are potential game-changers in the fight against viral pathogens. They are easy to produce, have limited cold chain requirements, and are expected to trigger a strong and lasting immune response. AstriVax Therapeutics is supported by well-known investors V-Bio Ventures, Fund+, Flanders Future TechFund managed by PMV, Thuja Capital, Ackermans & van Haaren, OMX Europe Venture Fund (Mérieux Equity Partners and Korys), BNP Paribas Fortis Private Equity, and the KU Leuven Gemma Frisius Fund. Founded in 2022, AstriVax Therapeutics is located in Leuven, Belgium. For more information, please visit <u>astrivax.com</u>.

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