Press Release

EnnoDC presents positive Phase I data at CROI 2025, demonstrating long-lasting immunity induced by Antibody Mediated Vaccines (AMVs)

Findings in HIV highlight AMV technology's versatility, robust immune response, and excellent safety profile, underpinning company's expansion into oncology applications

Paris, France – March 13, 2025 – EnnoDC, a clinical-stage immunotherapy biotech pioneering Antibody Mediated Vaccines (AMVs), today announced the presentation of final results from the ANRS VRI06 Phase I trial (NCT04842682) at the 2025 Conference on Retroviruses and Opportunistic Infections (#CROI2025, San Francisco, USA abstract #426). Presented by **Prof. Yves Levy**,[1] the data demonstrate the ability of CD40.HIVRI.Env (AMV.HIVRI) to induce controlled, durable and potent immune responses with an excellent safety profile in non-HIV infected volunteers, further validating the transformative potential of the AMV approach in infectious diseases and cancer.

AMVs are a new class of immunotherapy that combines the targeted action of an immunomodulatory antibody with the long-lasting effect of a vaccine. Thanks to its head (a CD40 dendritic cell engager) and tail (a commutable antigen from virus or tumor), each AMV induces a specific, controlled and broad immune response.

The ANRS VRI06 trial was the first in human clinical trial assessing the safety and immunogenicity of an AMV targeting the HIV envelope in non-HIV infected human volunteers.

Results of the first phase of the ANRS VRI06 trial showed a good safety profile and strong immunogenicity of CD40.HIVRI.Env (AMV.HIVRI). These immune responses mobilized both antibody- and cell-mediated immunity and persisted until week 48, 6 months after the last boost (Y. Levy et al., EClinicalMedicine, 2024). The long-term follow-up of this study was aimed to evaluate the durability of these responses and the booster effect of a single new injection (late boost) of CD40.HIVRI.Env (AMV.HIVRI), with or without adjuvant. Results presented at the CROI 2025 demonstrated the durability of these responses in median 80 weeks after ANRS VRI06 study entry: a single boost of low dose, even un-adjuvanted, of the AMV was sufficient to extend these responses 6 months following the late boost.

"These compelling results in HIV reinforce our confidence in the AMV platform's unique ability to deliver potent, long-lasting immune responses, making it an ideal candidate for advancing next-generation oncology therapies, particularly in HPV-induced cancers," said **Christophe Hubert, CEO of EnnoDC.**

"These data establish a clinical proof-of-concept for AMVs in HIV, demonstrating the ability of our AMV studio to engage, prime and activate Dendritic Cells, in vivo, to drive a highly controlled and sustained immune response," said **Prof. Yves Levy, co-founder and Chief Scientific Officer of EnnoDC**. *"This is an important milestone, not only for our HIV program but for the broader application of AMVs in oncology, where we are actively advancing novel therapeutic options."*

Building momentum: positive Immuno-Oncology data at ESMO IO 2024

EnnoDC recently reported encouraging initial clinical data for its oncology AMV candidate CD40.HVac (AMV.HPVE6E7) at the 2024 ESMO Immuno-Oncology (IO) Congress. This novel class of immunotherapy, currently in a Phase 1/2a trial for HPV-positive oropharyngeal cancer, demonstrated:

- Robust HPV-specific CD4+ and CD8+ T cell activation
- A favorable safety profile, reinforcing its potential as a differentiated cancer immunotherapy, alone and in combination

Pioneering AMVs in Immuno-Oncology

Building on positive infectious disease results, EnnoDC is now rapidly advancing its AMV technology to cancer immunotherapy. Current Immuno-Oncology pipeline highlights include:

- AMV.HPVE6E7 (lead candidate): Phase 1/2a trial in HPV-positive oropharyngeal cancer, showing early signs of tumor regression, strong immunogenicity, and a favorable safety profile
- AMV.PCA: a next-generation AMV candidate targeting prostate cancer, designed to overcome immune evasion mechanisms that have limited the success of immunotherapy in this indication to date

EnnoDC is at the forefront of the next generation of cancer immunotherapies with its first-in-class approach based on AMVs.

[1] *Un-adjuvanted CD40.HIVRI.Env vaccine late boost induces durable immune responses: ANRS VRI06 trial. Yves Levy, Christiane Moog, Aurélie Wiedemann, Melany Durand, Odile Launay, Fabio Candotti, Véronique, Rieux, Lucile Hardel, Alpha Diallo, Song Ding, Mireille Centlivre, Rodolphe Thiebaut, Giuseppe Pantaleo, Jean-Daniel Lelièvre, Laura Richert. Abstract 426, CROI 2025, March 9-12, San Francisco, USA*

About EnnoDC

EnnoDC is a French clinical-stage biotech pioneering Antibody Mediated Vaccines (AMVs), a novel class of immunotherapy fusing the power of antibodies and vaccines. AMV candidates engage, prime and activate Dendritic Cells *in vivo* to induce controlled, durable and potent broad immune response. The company's versatile AMV platform, validated in infectious disease studies, is now advancing two programs in immuno-oncology.

With a strong scientific foundation, strategic partnerships, and clear regulatory pathways, EnnoDC is actively engaging investors to accelerate its lead oncology programs to clinical inflection points.

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