

ReiThera Contributes GMP Manufacturing and Vector Platform to Phase 1 HIV Vaccine Trial in Africa

- **ReiThera manufactured the GRAdHIVNE1 vaccine candidate using its proprietary GRAd vector platform and GMP facility**
- **The trial, now underway in South Africa and Zimbabwe, is evaluating safety and T cell-mediated immunogenicity**
- **The program is funded by the Gates Foundation and driven by a global consortium including the Ragon Institute (MA, USA), IAVI (NY, USA) and a number of African clinical and research centers, with Dr. Tariro Makadzange, Executive Director and Founder of the Mutala Trust (Harare, Zimbabwe) as the clinical trial lead**
- **A joint press release issued by the full consortium provides further details on the study design and broader collaboration framework**

Rome, Italy, August 4, 2025 - ReiThera Srl, a biotechnology company specialized in viral vector development and GMP manufacturing, is proud to support the launch of a Phase 1 clinical trial in Africa of the HIV vaccine candidate GRAdHIVNE1. The vaccine, designed to induce potent T cell responses against critical regions of the HIV virus, is now being tested in healthy volunteers and people living with HIV in Zimbabwe and South Africa.

The clinical trial is sponsored by IAVI and conducted in collaboration with leading African clinical and research institutions, the Ragon Institute of Mass General Brigham, MIT, Harvard (the Ragon Institute) and ReiThera.

The program is funded by the Gates Foundation and is integral to the global effort of developing innovative approaches for HIV prevention tailored to the communities most affected by the epidemic.

ReiThera played a key role in the program by developing the viral vector platform and manufacturing the clinical trial material. The GRAd platform, based on a proprietary replication-deficient Gorilla adenovirus, is endowed with the property to induce strong CD8+ T cell responses and offers the advantage of low pre-existing immunity in humans.

"Our contribution to this important trial reflects ReiThera's ongoing commitment to applying innovative technology and high-standard GMP manufacturing to global health challenges," said Stefano Colloca, CEO and co-founder of ReiThera. "We're proud to collaborate with IAVI, the Ragon Institute, and African research leaders on a project with the potential to reshape HIV vaccine development. We sincerely thank all the partners, researchers, and teams whose dedication and expertise have made this milestone possible."

The GRAdHIVNE1 trial, known as IAVI C114, will enroll around 120 participants and assess both the safety and immunogenicity of the vaccine candidate. Clinical trial sites include the Mutala Trust Clinical Trial Site in Harare, Zimbabwe; the Desmond Tutu Health Foundation in Cape Town, South Africa; and the Africa Health Research Institute in Durban, South Africa.

ReiThera continues to support the development of innovative vaccines and advanced therapies through its integrated capabilities in vector engineering, process development, and GMP manufacturing.

For additional information on the broader collaboration and trial, please refer to the joint press release issued by the partner organizations.

About ReiThera Srl.

ReiThera Srl, an Italian CDMO specializing in technology and process development as well as GMP manufacturing of viral vectors for genetic vaccines and advanced therapies, is the developer and owner of the GRAd platform used for this HIV vaccine.

About IAVI

IAVI is a global nonprofit scientific organization that works to develop vaccines and antibodies to prevent HIV and other infectious diseases, with a focus on innovation and equitable access. IAVI is the sponsor of this trial. Read more at www.iavi.org

About Mutala Trust

Mutala Trust is founding member of Africa Clinical Research Network (ACRN) and is a site based in Harare, Zimbabwe. It is known for conducting high-quality, ethically sound clinical trials addressing diseases that affect African communities. Mutala is the clinical lead site for the study.

About the Ragon Institute of Mass General Brigham, MIT, and Harvard

The Ragon Institute of Mass General Brigham, MIT, and Harvard was established with a collaborative scientific mission among these institutions that brings scientists, clinicians and engineers together to harness the immune system to combat and cure human disease. They contributed to vaccine design. For more information, visit www.ragoninstitute.org