NEWS RELEASE

IAVI and Moderna Launch First-in-Africa Clinical Trial of mRNA HIV Vaccine Development Program

5/18/2022

Phase I trial in Rwanda and South Africa aims to evaluate mRNA HIV vaccine antigen for safety and immunogenicity and strengthen regional scientific capacity

NEW YORK, NY and CAMBRIDGE, MA / ACCESSWIRE / May 18, 2022 / The nonprofit scientific research organization IAVI and Moderna, Inc. (Nasdaq:MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the first participant screenings are soon to start for a Phase I clinical trial of an mRNA HIV vaccine antigen (mRNA-1644) at the Center for Family Health Research (CFHR) in Kigali, Rwanda, and The Aurum Institute in Tembisa, South Africa.

The IAVI-sponsored trial, IAVI G003, builds on progress in HIV vaccine research. Recent **findings** from the Phase I clinical trial IAVI G001 showed that vaccination with the HIV immunogen eOD-GT8 60mer as a recombinant protein safely induced the targeted immune responses in 97% of recipients (healthy U.S. adults). The immune response - targeting and expanding a specific class of B cells - is needed to start the process of developing broadly neutralizing antibodies (bnAbs). The induction of bnAbs is widely considered to be a goal of an efficacious HIV vaccine, and this B-cell activation is the first step in that process. IAVI G003 is designed to test the hypothesis that vaccination with eOD-GT8 60mer, developed by scientific teams at IAVI and Scripps Research, delivered via Moderna's mRNA platform, can induce similar immune responses in African populations as was seen for IAVI G001.

IAVI G003 is made possible by the support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID). Additional support is provided by the Bill & Melinda Gates Foundation through grants to Moderna and to the Collaboration for AIDS

Vaccine Discovery (CAVD) Vaccine Immunology Statistical Center (VISC).

"The road to an HIV vaccine has been long and winding. mRNA technology has the potential to accelerate the development of a safe, effective, affordable, and durable HIV vaccine for use throughout the world," said Mark Feinberg, M.D., Ph.D., president and CEO of IAVI. "IAVI G003 harnesses Moderna's proven mRNA vaccine technology, a novel HIV vaccine approach developed over many years by IAVI and Scripps Research, and more than two decades of collaboration with scientific centers of excellence in sub-Saharan Africa, supported by USAID. Together, we aim to answer critical research questions that can advance HIV vaccine development that increasingly involves leadership by scientists in countries where a vaccine is needed most."

"With our mRNA technology and IAVI's discovery and development expertise, we are looking forward to advancing a novel approach to overcome some of the longstanding hurdles to developing a protective HIV vaccine. Moreover, we are grateful for the opportunity to work in partnership with researchers and scientists from communities heavily burdened by HIV," said Stéphane Bancel, CEO of Moderna. "Moderna's HIV vaccine development program, together with our portfolio of COVID-19, Zika, and Nipah programs, advances 4 of the 15 priority vaccine programs we **committed** to develop by 2025, targeting infectious diseases that threaten global health."

Trial sites are expected to enroll a combined total of 18 healthy, HIV-negative adult volunteers for IAVI G003. All participants will receive two doses of eOD-GT8 60mer mRNA, which contains a portion of the viral sequence and cannot cause an infection with HIV. There is no blinding and no randomization in this open-label study; all participants will receive the intervention. Enrolled participants will be monitored for safety for six months after receipt of the last dose, and their immune responses will be examined in molecular detail to evaluate whether the targeted responses will be achieved. The primary trial endpoints are safety and immunogenicity, defined as the ability of a substance to elicit an immune response.

Trial endpoint analysis for IAVI G003 will be conducted using immunological assays and completed primarily by scientists at the KAVI-Institute for Clinical Research (KAVI-ICR) in Nairobi, Kenya; the Kenya Medical Research Institute-Centre for Geographic Medicine Research-Coast (KEMRI-CGMRC) in Kilifi, Kenya; and in part by scientists at the CAVD-Central Services Facility; **IAVI's Neutralizing Antibody Center** (IAVI NAC) at Scripps Research, in La Jolla, California; and the VISC.

The CFHR, Aurum Institute, KAVI-ICR, and KEMRI-CGMRC are part of the Accelerate the Development of Vaccines and New Technologies to Combat the AIDS Epidemic (ADVANCE) program and the IAVI-ADVANCE **Partner Clinical Research Center (CRC) Network**. ADVANCE is a 10-year cooperative agreement with PEPFAR through USAID that provides a platform to further development of an efficacious HIV/AIDS vaccine and strengthen vaccine research capacities in Africa. This initiative has enabled African research institutions and scientists to play key roles in the design and evaluation of novel biomedical prevention products using promising technologies.

ADVANCE collaborators will engage IAVI G003 study participants in parallel socio-behavioral research to understand the acceptability of sampling techniques - fine needle aspiration (FNA), leukapheresis, and blood draws - used in the trial and the impact of trial participation on individuals and their communities.

"I think this is a revolutionary approach to HIV vaccine design and development, and I am hopeful that we are on the path to finally realizing an HIV vaccine," said Etienne Karita, M.D., M.Sc., M.S.P.H., director of CFHR. "This is the first time we are evaluating an mRNA-delivered HIV immunogen in Africa with African scientists and researchers at the helm, building on our longstanding partnerships with USAID and IAVI."

"Aurum has a long history of being involved in vaccine trials, and we have significantly expanded our footprint and scientific capacity in South Africa over the last 15 years in partnership with IAVI and USAID," said Vinodh Edward, D.Tech., CEO of Aurum South Africa. "It is exciting for us to be applying that capacity to testing a next-generation HIV vaccine antigen using mRNA. We've seen the impact mRNA technology has had on COVID-19, and we look forward to seeing how it can potentially impact HIV."

"IAVI G003 is more than just a clinical trial. This is a first-of-its-kind collaboration to advance emerging science and a new generation of African scientists who are taking HIV vaccine development into the future. USAID is proud to support this historic effort," said Margaret McCluskey, R.N., M.P.H., M.P.S., senior technical advisor for HIV vaccine research at USAID.

eOD-GT8 60mer was originally developed as a protein by William Schief, Ph.D., professor at Scripps Research and executive director of vaccine design at **IAVI's Neutralizing Antibody Center** (IAVI NAC), and collaborators. The immunogen eOD-GT8 60mer is designed to be part of an eventual multi-step vaccination regimen that will stimulate an immune response to elicit bnAbs that neutralize, or block, HIV infection. On its own, eOD-GT8 60mer will not lead to this outcome, but IAVI G003 will yield important safety and immunogenicity data about this vaccine antigen in a population of healthy adults residing in the part of the world most severely affected by HIV. Years of work in a long-standing NAC partnership between IAVI and Scripps Research have enabled the development of this immunogen. The organizations will continue to collaborate as they extend and evaluate the sequence of promising immunogens to elicit bnAbs. IAVI and Moderna are evaluating mRNA delivery of eOD-GT8 60mer followed by a boosting immunogen in a **Phase I clinical trial** in U.S. populations.

IAVI and Scripps Research developed eOD-GT8 60mer mRNA with support from the Gates Foundation, the Center for HIV/AIDS Vaccine Immunology and Immunogen Discovery (CHAVI-ID) at the U.S. National Institute for Allergy and Infectious Diseases at the U.S. National Institutes of Health, and Moderna. Research at the IAVI NAC that contributed to the development of eOD-GT8 60mer mRNA was also made possible by the government of the Netherlands through the Ministry of Foreign Trade & Development Cooperation and through the generous support

of the American people through the PEPFAR through USAID. The content of this press release is the responsibility of IAVI and Moderna and does not necessarily reflect the views of USAID or the United States government.

About IAVI

IAVI is a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges including HIV, tuberculosis, and emerging infectious diseases. Its mission is to translate scientific discoveries into affordable, globally accessible public health solutions. Read more at **iavi.org**.

About Moderna

In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for rapid clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators, which has allowed for the pursuit of both groundbreaking science and rapid scaling of manufacturing. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and auto-immune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past seven years. To learn more, visit **www.modernatx.com**.

Moderna's Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the ability of eOD-GT8 60mer, delivered via Moderna's mRNA platform, to induce immune responses; the potential of mRNA technology to accelerate the development of an HIV vaccine; Moderna's plans to advance 15 priority vaccine programs by 2025; and expected enrollment in and conduct of IAVI G003. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and

Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at **www.sec.gov**. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.

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SOURCE: Moderna, Inc.

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