IAVI and Moderna Launch Trial of HIV Vaccine Antigens Delivered Through mRNA Technology

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Phase 1 trial aims to build on response seen in proof-of-concept trial

CAMBRIDGE, MA and NEW YORK, NY / ACCESSWIRE / January 27, 2022 / IAVI, the nonprofit scientific research organization, and biotechnology company Moderna announced today that first doses have been administered in a clinical trial of experimental HIV vaccine antigens at George Washington University (GWU) School of Medicine and Health Sciences in Washington, D.C.

The Phase 1 trial, IAVI G002, is designed to test the hypothesis that sequential administration of priming and boosting HIV immunogens delivered by messenger RNA (mRNA) can induce specific classes of B-cell responses and guide their early maturation toward broadly neutralizing antibody (bnAb) development. The induction of bnAbs is widely considered to be a goal of HIV vaccination, and this is the first step in that process. The immunogens being tested in IAVI G002 were developed by scientific teams at IAVI and Scripps Research and will be delivered via Moderna’s mRNA technology.

"We are tremendously excited to be advancing this new direction in HIV vaccine design with Moderna's mRNA platform. The search for an HIV vaccine has been long and challenging, and having new tools in terms of immunogens and platforms could be the key to making rapid progress toward an urgently needed, effective HIV vaccine," says Mark Feinberg, M.D., Ph.D., president and CEO of IAVI. "We are grateful to all of our partners and especially to the Bill & Melinda Gates Foundation for funding this trial."

"We are very pleased to be partnering with IAVI and the Bill & Melinda Gates Foundation to apply our mRNA
technology in the setting of HIV. At Moderna, we believe that mRNA offers a unique opportunity to address critical unmet public health needs around the world," said Stephen Hoge, M.D., President of Moderna. "We believe advancing this HIV vaccine program in partnership with IAVI and Scripps Research is an important step in our mission to deliver on the potential for mRNA to improve human health."

The HIV vaccine antigens being evaluated as mRNA in this study were originally developed as proteins by William Schief, Ph.D., professor at Scripps Research and executive director of vaccine design at IAVI's Neutralizing Antibody Center (NAC), and colleagues. In 2021, Dr. Schief announced results from the IAVI G001 clinical trial, showing that an adjuvanted protein-based version of the priming immunogen (eOD-GT8 60mer) induced the desired B-cell response in 97% of recipients. IAVI G002 not only tests priming of the desired immune response using mRNA delivery of eOD-GT8 60mer, but also assesses the ability of a boosting immunogen to induce further maturation of B cells. Given the speed with which mRNA vaccines can be produced, this platform offers a more nimble and responsive approach to vaccine design and testing, potentially shaving off years from typical vaccine development timelines.

The Schief lab has been a pioneer of the vaccine design approach known as germline targeting. Naive B cells display antibodies encoded by unmutated, or "germline" genes. A series of vaccines, which would begin with the prime-boost immunogens tested here, may be able to target specific naive B cells and induce them to mature into bnAb-producing ones. In the lab, bnAbs have been shown to neutralize a broad range of HIV variants, and one bnAb, VRC01, was recently shown to be capable of protecting humans against infection by neutralization-susceptible HIV strains. VRC01 is a member of the class of bnAbs targeted in IAVI G001.

"We've seen promising proof of concept for germline targeting in IAVI G001, and this trial lets us take that approach to the next stage. What's more, we've been able to expedite production of clinical trial material at a remarkably rapid pace because of Moderna's technology," said Schief.

Years of work in a long-standing NAC partnership between IAVI and Scripps Research have enabled the development of these vaccine antigens. The organizations will continue to collaborate as they extend and evaluate the sequence of promising immunogens to elicit bnAbs.

IAVI G002 is sponsored by IAVI and takes place at four sites: GWU School of Medicine and Health Sciences (lead investigator David Diemert, M.D.), Hope Clinic of Emory Vaccine Center in Atlanta (lead investigator Srilatha Edupuganti, M.D.), Fred Hutchinson Cancer Research Center (Fred Hutch) in Seattle (lead investigator Julie McElrath, M.D., Ph.D.), and the University of Texas-Health Science Center at San Antonio (lead investigator Barbara Taylor, M.D., M.S.). The sites will enroll 56 healthy, HIV-negative adult volunteers. Forty-eight participants will receive one or two doses of eOD-GT8 60mer mRNA Vaccine (mRNA-1644), with 32 of them receiving the boost Core-g28v2 60mer mRNA Vaccine (mRNA-1644v2-Core). An additional eight volunteers will receive the boost immunogen alone.
Participants will be monitored for safety for six months after last vaccination. Participants’ immune responses to the vaccine candidates will be examined in molecular detail to evaluate whether the targeted responses were achieved.

Diemert said, “We at GWU School of Medicine and Health Sciences are pleased to be part of this endeavor that aims to induce the next step of B-cell maturation toward the goal of generating antibodies that can neutralize a broad range of HIV variants. Further immunogens will be needed to guide the immune system on this path, but this prime-boost combination could be the first key element of an eventual HIV immunization regimen.”

The Collaboration for AIDS Vaccine Discovery (CAVD) Comprehensive Cellular Vaccine Immune Monitoring Consortium/the Dale and Betty Bumpers Vaccine Research Center at the National Institute of Allergy and Infectious Diseases (NIAID)/National Institutes of Health (NIH), the CAVD Comprehensive Antibody Vaccine Immune Monitoring Consortium, Duke University’s Human Vaccine Institute, Fred Hutch, and the Karolinska Institute will be performing key analytical assays in support of the trial, to assess whether the targeted immune response is elicited. The CAVD Vaccine Immunology Statistical Center played an important role contributing to the study design, analytical methods development, and data evaluation. In January 2016, Moderna entered a global health project framework agreement with the Bill & Melinda Gates Foundation to advance mRNA-based development projects for various infectious diseases.

IAVI and Scripps Research developed the eOD-GT8 60mer and Core-g28v2 60mer mRNA candidates with support from the Bill & Melinda Gates Foundation, the Center for HIV/AIDS Vaccine Immunology and Immunogen Discovery (CHAVI-ID) at NIAID at the NIH, and Moderna.

Research at the IAVI NAC that contributed to the development of the vaccine candidates 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 U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID). The contents are the responsibility of IAVI and Moderna and do 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 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 both clinical and commercial production at scale and at unprecedented speed. 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 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 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: Moderna's collaboration with IAVI to develop a vaccine candidate against HIV; the potential for the vaccine candidate to induce a B-cell response and to trigger neutralizing antibody development and to protect against HIV infection; the speed with which vaccines can be developed using an mRNA platform; and the future conduct of clinical trials for the vaccine candidate. 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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