

March 5, 2024



AIDS Clinical Trial Group Presents Results from Phase 1 Study of ModeX Trispecific Antibody for the Treatment and Prevention of HIV

- *Study delivers first clinical safety and pharmacokinetic data as proof of concept for the use of multispecific antibodies in humans*
- *Candidate showed similar half-life to standard monoclonal antibodies and minimal anti-drug antibodies*

WESTON, Mass., March 05, 2024 (GLOBE NEWSWIRE) -- ModeX Therapeutics Inc., an OPKO Health company (NASDAQ: OPK), today announced results from a Phase 1 clinical study of SAR441236, its trispecific broadly neutralizing antibody against the human immunodeficiency virus (HIV), at the 2024 Conference on Retroviruses and Opportunistic Infections (CROI) in Denver, Colorado. These clinical data are the first reported for a trispecific antibody and specifically provide support for the further development of multispecific, multivalent antibodies against HIV as a differentiated approach to addressing HIV infection.

The study enrolled 52 participants and was conducted by the AIDS Clinical Trials Group (ACTG), a clinical trials network funded by the National Institute of Allergy and Infectious Diseases, NIH. The observed antibody half-life was 38 ± 10 days. The antibody was safe and well-tolerated at all dose levels and via both intravenous and subcutaneous administration. Dosing ranged from 0.3 mg/kg to 30 mg/kg with up to 4 administrations, and observed pharmacokinetics remained consistent in all dosing regimens.

Broadly neutralizing antibodies such as SAR441236 are of interest for their novel mechanisms that may offer longer-lasting treatment and prevention to a wide range of HIV strains as the virus continues to evolve. Their complex interactions with other components of the immune system may also offer opportunities for long-term remission of HIV infection.

"This study represents a milestone in the development of multispecific antibodies, demonstrating key parameters of pharmacokinetics and safety. The study's full data set inform our ongoing development of multispecific antibodies to prevent or treat HIV infection," said Dr. John Mascola, Chief Scientific Officer of ModeX. "Existing oral antiretroviral therapies are a powerful tool in the fight against HIV, but multispecific antibodies offer long-lasting preventative and treatment options against a broad swathe of variants, with the possibility of activating the immune system against the latent virus population to effect a functional cure."

The development of SAR441235 is a result of a collaboration between ModeX and the Vaccine Research Center of the National Institute of Allergy and Infectious Disease, NIH. SAR441236 binds to three parts of HIV simultaneously and is engineered with amino acid

modifications in its Fc-region for half-life extension. In preclinical studies, the candidate provided protection against multiple strains of simian HIV *in vivo* and showed broad neutralizing activity against a wide range of viral strains *in vitro*. Further analyses from the clinical study are ongoing, including analyses of antiviral efficacy in viremic participants and effects on the HIV-1 reservoir (infected cells that do not actively produce virus) in aviremic participants. These clinical data on an HIV multispecific antibody inform the future advancement of such antibodies for the prevention and treatment of HIV and provide strong rationale for the development of current and future antibody products.

About ModeX Therapeutics

ModeX Therapeutics is a clinical-stage biopharmaceutical company developing innovative multispecific biologics for cancer and infectious disease. Its platforms unite the power of multiple biologics in a single molecule to create multispecific antibodies and vaccines with unprecedented versatility and potency in fighting complex disease. The ModeX pipeline includes candidates against both solid and hematologic tumors, as well as several of the world's most pressing viral threats. Its founding team includes globally recognized medical innovators with proven track records of delivering breakthroughs for patients. ModeX is an OPKO Health company based in Weston, Massachusetts. For more information, please visit www.modextx.com.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding whether the data presented support further development as a differentiated approach to addressing HIV infection, the expected benefits of utilizing broadly neutralizing antibodies in the treatment and prevention of HIV strains or whether they would offer opportunities for long-term remission of HIV infection or whether multispecific antibodies offer better or longer lasting preventative and treatment options against HIV variants or other viruses, whether these antibodies or any multispecific antibodies will be successfully developed or commercialized, expectations regarding market potential, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including the risks that the any clinical trials or studies utilizing these or other multispecific antibodies against HIV or other viruses may not be successful or achieve the expected results or effectiveness, and may not generate data that would support the approval or marketing products for the indications being studied, that others may develop superior products and that multispecific antibody treatments may not have advantages or prove to be superior over presently marketed products or products

introduced in the future. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

Contacts:

Investors:

LHA Investor Relations
Yvonne Briggs, 310-691-7100
ybriggs@lhai.com

or

Bruce Voss, 310-691-7100
bvoss@lhai.com

Media:

ModeX Media Relations
media@modextx.com



Source: OPKO Health, Inc.