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OPKO Health's ModeX Therapeutics Announces Epstein-Barr Virus Vaccine Candidate Enters Phase I Clinical Study in Collaboration with Merck

- Epstein-Barr virus (EBV) causes infectious mononucleosis and is associated with several types of cancer and multiple sclerosis
- There are no current treatments or vaccines for EBV
- First participant dosed with novel investigational EBV vaccine targeting multiple viral proteins in Phase I study

WESTON, Mass., Jan. 07, 2025 (GLOBE NEWSWIRE) -- ModeX Therapeutics Inc., an OPKO Health company (NASDAQ: OPK), announces dosing of the first participant in the Phase I study ([NCT06655324](#)) of an EBV vaccine candidate being developed in [collaboration with Merck](#), known as MSD outside the United States and Canada. This development triggers an undisclosed cash milestone payment from Merck to ModeX.

"EBV infection can cause serious illness and pose long-term risks of cancer and autoimmunity. Through our collaborators at Merck, human trials to advance a novel vaccine candidate have now begun. Our nanoparticle vaccine aims to stimulate protective immunity in patients and prevent these diseases," said Gary Nabel, M.D., Ph.D., President and Chief Executive Officer of ModeX and Chief Innovation Officer of OPKO.

The investigational vaccine based on MDX2201 is being evaluated for safety and tolerability in up to 200 healthy adults against EBV.

"We are grateful to the participants and physicians who are actively engaged with Merck in our joint efforts to explore the potential of MDX2201 as a novel vaccine against EBV," said Elias Zerhouni, M.D., President and Vice Chairman of OPKO. "Our Merck collaboration combines their discovery and clinical development expertise with our innovative and unique technology platform against this latent virus where an approved vaccine could have significant implications for the majority of people around the world."

About MDX2201

MDX2201 is based on ModeX's ferritin nanoparticle vaccine platform, which can express as many as 24 copies of a recombinant antigen on its surface to enhance the presentation of key components of the virus and stimulate durable protective immunity. MDX2201 presents antigens from four viral proteins involved in viral entry into host cells. These include a recombinant antigen designed from the proteins gH, gL and gp42, as well as an antigen derived from gp350. By using ModeX's multi-targeted approach, this combination inhibits infection in two cell types, B cells and epithelial cells, which contrasts from efforts that previously focused on gp350 alone. This EBV vaccine technology was the subject of

preclinical data published in May 2022 in Science Translational Medicine.

About Epstein-Barr Virus

Epstein-Barr virus (EBV), a member of the herpes virus family, is one of the most common human viruses. Most people are infected with EBV at some point during their lives. EBV can cause [infectious mononucleosis](#), also called mono, and is associated with other illnesses, including some specific types of cancer and multiple sclerosis. There are currently no FDA approved vaccines or treatments for EBV infection.

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, an OPKO Health company, is 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, please visit www.opko.com.

Cautionary Statement Regarding Forward-Looking Statements

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," "could," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including whether and when the Phase I study will be completed, and whether final study data will be positive and support marketing approval, the ability to develop and commercialize MDX2201, whether MDX2201 is capable of effectively protecting patients against EBV and related disease, whether MDX2201 will be safe, or have any impact on the severity of disease, expectations regarding the product, its efficacy and safety 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 Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in our other filings with the Securities and Exchange Commission, as well as liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, the success of our relationship with our commercial partners, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, and that currently available

over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. 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.

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1. Dowd, et al. Seroprevalence of Epstein-Barr Virus Infection in US Children Ages 6-19, 2003-2010. [doi: 10.1371/journal.pone.0064921](https://doi.org/10.1371/journal.pone.0064921)



Source: OPKO Health, Inc.