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OPKO Health's ModeX Therapeutics Enters into Exclusive Worldwide License and Collaboration Agreement with Merck to Develop Epstein-Barr Virus Vaccine Candidate

- *MDX-2201 leverages ModeX's innovative biologics platform to target multiple Epstein-Barr virus (EBV) proteins*
- *EBV is the leading cause of infectious mononucleosis and is also associated with some specific types of cancer*

MIAMI, March 08, 2023 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ: OPK) today announced that ModeX Therapeutics, Inc., an OPKO Health company, entered into an exclusive worldwide license and collaboration agreement with Merck, known as MSD outside the United States and Canada, for the development of MDX-2201, ModeX's preclinical nanoparticle vaccine candidate targeting EBV.

"We are delighted to enter this collaboration with Merck to develop a vaccine against EBV, a virus that takes a profound toll on human health worldwide. Targeting four proteins used by EBV to infect cells, this vaccine candidate embodies the novel multitargeting approach developed by ModeX scientists," said Gary Nabel, M.D., Ph.D., President and Chief Executive Officer of ModeX and Chief Innovation Officer of OPKO.

Under the terms of the agreement, OPKO will receive an upfront payment of \$50 million and is eligible for milestone payments associated with progress in the development and commercialization of MDX-2201 of up to \$872.5 million, as well as royalties on global sales.

ModeX and Merck will jointly advance MDX-2201 to an Investigational New Drug (IND) application filing, after which Merck will be responsible for clinical and regulatory activities, as well as product commercialization. Pre-IND filing activity will be guided by a joint steering committee comprised of representatives from both companies.

"We founded ModeX to develop innovative multispecific biologics for cancer and infectious diseases that target multifactorial pathways that cause illness," said Elias Zerhouni, M.D., President and Vice Chairman of OPKO. "This first collaboration leverages our scientific excellence and innovative platforms along with Merck's discovery and clinical development expertise with the goal of benefiting patients around the world."

"Through the acquisition of ModeX, we broadened our technology foundation and expanded our product pipeline into new therapeutic areas," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "Merck represents the ideal partner to develop and commercialize a new vaccine candidate, and we are particularly proud to enter into this high-

potential agreement so soon after completing the ModeX transaction last May.”

“At Merck we have a proud legacy of developing vaccines including several that have the potential to help protect against certain types of cancer,” said Tarit Mukhopadhyay, Ph.D., Vice President, Infectious Diseases and Vaccine Discovery, Merck Research Laboratories. “We look forward to working with the ModeX Therapeutics team to apply our experience and expertise to evaluate the potential of MDX-2201 to help protect against EBV infection and other, potentially related, conditions.”

About MDX-2201

MDX-2201 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. MDX-2201 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](#). ModeX scientists previously worked at the Vaccine Research Center, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and Sanofi in the early development of this vaccine candidate. This project also involved collaboration with scientists at the Laboratory of Infectious Diseases, NIAID.

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 is an OPKO Health company based in Natick, 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.

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," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding product development efforts, expected benefits of MDX-2201 and ModeX's ferritin nanoparticle vaccine platform, whether the collaboration with Merck will be successful, whether clinical trials for MDX-2201 will support marketing approval, whether MDX-2201 will be successfully developed or commercialized or meet expectations regarding its efficacy, safety and market potential, whether OPKO will receive milestone or royalty payments for development and commercialization of MDX-2201, expectations about the global EBV market, whether MDX-2201 has the potential to be first in class and will be approved by the FDA, as well as other non-historical statements, including statements about our expectations, products, beliefs or intentions regarding ModeX, projected future clinical developments, the potential for ModeX products and pipeline and any other statements regarding OPKO's and ModeX's future expectations, beliefs, plans, product candidates, objectives, financial conditions, assumptions or future events or performance. 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 under the heading "Risk Factors" in our other filings with the Securities and Exchange Commission. 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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