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OPKO Health's ModeX Therapeutics Begins Clinical Trial of MDX2004 for the Treatment of Advanced Cancers

First patient dosed in Phase 1/2a study with novel immune rejuvenator, a trispecific antibody-fusion protein

Two MDX2004 abstracts accepted for poster presentation at SITC Annual Meeting 2025

WESTON, Mass., Oct. 28, 2025 (GLOBE NEWSWIRE) -- ModeX Therapeutics Inc., an OPKO Health company (NASDAQ: OPK), today announced the initiation and recent dosing of the first patient in a Phase 1/2a clinical trial ([NCT07110584](https://clinicaltrials.gov/ct2/show/study/NCT07110584)) with MDX2004, a first-in-class trispecific antibody-fusion protein for oncology and immune disorders. The study is designed to evaluate the safety, tolerability, and biologic activity of MDX2004 as an immunotherapy for advanced cancers.

MDX2004 is designed to stimulate T cells through three signaling pathways to enhance immune activation. This proprietary multispecific antibody engages CD3, CD28, and 4-1BB and is expected to activate T lymphocytes, including stem and memory T cells. Because stem T cells undergo self-renewal and give rise to mature T cells, the drug aims to recruit and replenish, or "rejuvenate," cellular immunity. Unlike previous 4-1BB antibody therapies, recognition of 4-1BB by this molecule does not involve antibody binding because it binds as a ligand to the natural receptor.

"Patients with advanced solid tumors may have limited options with existing treatments, facing challenging disease control rates and low long-term survival," said Giovanni Abbadessa, M.D., Ph.D., Chief Medical Officer of ModeX. "The MDX2004 multispecific antibody aims to rejuvenate T cells and sustain an expanded immune response in a broad range of tumors. We look forward to exploring further via this clinical trial."

"We are excited to bring MDX2004 to patients as a first-in-class trispecific antibody with a unique design aiming for a specific mechanism of action. By stimulating and sustaining immune function, this T cell rejuvenator has potential to treat diverse cancers and reverse immune impairment caused by chemotherapy, chronic diseases, infection and aging," said Phillip Frost, M.D., Chairman and CEO of OPKO Health and Gary Nabel, M.D., Ph.D., President and CEO of ModeX and Chief Innovation Officer of OPKO Health.

Preclinical proof-of-concept data as well as clinical dose selection analyses to support the MDX2004 development will be showcased in two poster presentations at the 40th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), National Harbor, MD, on November 5-9, 2025.

About MDX2004

MDX2004 is a novel trispecific antibody–fusion protein that targets CD3, CD28, and 4-1BB

(CD137) on human T cells. It is designed to promote the expansion of stem and memory T cell populations, thereby rejuvenating immune function and enhancing anti-tumor immunity. This trifunctional approach aims to expand and sustain both stem and mature memory T cell subsets, which have been associated with favorable responses to immunotherapy. It may thus help restore immune function in subjects with underlying immune impairment from aging, chronic diseases such as diabetes, infections or chemotherapies.

Beyond bispecifics: ModeX Synergistic Targeting of Antibody Receptors (MSTAR)

Multispecific antibody therapeutics can help generate medicines of the future by targeting multiple disease pathways simultaneously. Many untreatable or complex conditions arise from multiple root causes; yet most medicines only act on a single target. ModeX overcomes these challenges by combining natural protein structures using a platform known as the ModeX Synergistic Targeting of Antibody Receptors (MSTAR) to create unique multispecific medicines. The platform generates multispecific antibodies from modular building blocks intended to modulate potency and maximize specificity to address multiple disease pathways simultaneously.

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, Mass. 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," "could," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including whether and when we will initiate and complete the clinical studies contemplated for MDX2004 and whether final study data will be positive, whether data will support marketing approval, our ability to develop and commercialize MDX2004, whether MDX2004 is capable of effectively treating patients with certain cancers, whether MDX2004 will be safe, or have any impact on the severity of disease, expectations regarding the product, its efficacy, safety and 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 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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