

April 22, 2026



OPKO Health's ModeX Therapeutics Begins Clinical Trial of Tetraspecific Antibody for Treatment of B-cell Lymphomas

Patients dosed in Phase 1 safety and tolerability study of MDX2003, a novel T-cell engager designed to optimize killing of lymphomas

Preclinical studies presented at 2025 American Society of Hematology (ASH) Annual Meeting and ESMO Targeted Anticancer Therapies Congress 2026

WESTON, Mass., April 22, 2026 (GLOBE NEWSWIRE) -- ModeX Therapeutics Inc., an OPKO Health company (NASDAQ: OPK), today announced the dosing of patients with its first-in-class tetraspecific T-cell engager, MDX2003, for relapsed or refractory B-cell lymphoma. This multispecific antibody targets two proteins found on the surface of B-cell malignancies, CD19 and CD20, along with the CD3 and CD28 co-stimulatory T-cell activators to sustain T cell killing of these tumors.

The MDX-2003-101 study ([NCT07249905](#)) is designed to evaluate the safety, tolerability, pharmacokinetic, and immune activity of MDX2003 in adult patients with various types of B-cell lymphoma. The study includes dose-escalation and dose-expansion phases. B-cell lymphoma, a form of non-Hodgkin lymphoma arising from B lymphocytes, represents the most common lymphoma subtype, accounting for approximately 85% of cases¹. Despite available therapies, an estimated 30–40% of patients experience disease relapse, progression, or refractory disease following initial chemoimmunotherapy².

"This clinical trial represents a significant milestone for ModeX," said Giovanni Abbadessa, M.D., Ph.D., Chief Medical Officer of ModeX Therapeutics. "MDX2003 is designed to address limitations of current T-cell-engagers by combining dual tumor antigen targeting with optimized T-cell activation. This first-in-human study will allow us to assess safety and biologic activity in patients with advanced B-cell lymphoma."

Preclinical proof-of-concept data, along with analyses supporting clinical dose selection, were presented in poster presentations at the 2025 American Society of Hematology (ASH) Annual Meeting and ESMO Targeted Anticancer Therapies Congress 2026.

"MDX2003 takes advantage of our proprietary multispecific antibody design to optimize tumor killing and address the problem of immune escape in the treatment of lymphoma," 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. "This study will define dosing and treatment regimens for future efficacy trials."

About MDX2003

MDX2003 is a novel tetraspecific T-cell engager targeting CD19 and CD20 on B cells and CD3 and CD28 on T cells. This dual B-cell targeting strategy is intended to mitigate the impact of tumor antigen loss, while CD3/CD28 co-stimulation aims to promote robust T-cell activation, survival, and sustained cytotoxic activity. Preclinical studies have demonstrated potent anti-tumor activity and balanced T-cell activation, supporting advancement into clinical evaluation³.

About ModeX Therapeutics

ModeX Therapeutics is a clinical-stage biopharmaceutical company developing innovative multispecific biologics for cancer, immunology, and infectious diseases. Its platforms unite the power of multiple biologics in a single molecule to create multispecific antibody therapeutics designed to address complex diseases. The ModeX pipeline includes first-in-class candidates for oncology indications against both solid and hematologic tumors, autoimmune and immunological diseases, and for infectious disease indications against the most pressing viral threats. Its founding team includes globally recognized medical innovators with proven track records of delivering breakthrough medicines for patients. ModeX Therapeutics Inc., an OPKO Health company (NASDAQ: OPK), is based in Weston, Massachusetts. For more information, 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 complete the clinical studies contemplated for MDX2003 and whether final study data will be positive, whether data will support marketing approval, our ability to develop and commercialize MDX2003, whether MDX2003 is capable of effectively treating patients with certain cancers, whether MDX2003 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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¹Silkenstedt E, Salles G, Campo E, Dreyling M. B-cell non-Hodgkin lymphomas. *Lancet*. 2024 May 4;403(10438):1791-1807. doi: 10.1016/S0140-6736(23)02705-8. PMID: 38614113; PMCID: PMC12261310.

²Sehn L.H., Salles G. Diffuse Large B-Cell Lymphoma. *N. Engl. J. Med.* 2021;384:842–858. doi: 10.1056/NEJMr2027612.

³Wei R, Wu L, Kramer J et al. MDX2003, a novel tetraspecific T-cell engager-expander targeting CD19xCD20xCD3xCD28, demonstrates potent preclinical activity against B-cell malignancies. Presented at: ASH 2025; December 6-9, 2025; Orlando, FL. Paper 3311.



Source: OPKO Health, Inc.