



Xilio Therapeutics Announces First Patient Dosed in Phase 1/2 Clinical Trial of XTX501 in Patients with Metastatic NSCLC

October 26, 2026

XTX501 is a novel PD-1/masked IL-2 bispecific that has the potential to become a foundational backbone regimen for solid tumors

Anticipate reporting initial Phase 1 data in the fourth quarter of 2027

Plan to present a trial-in-progress poster for XTX501 at the Society for Immunotherapy of Cancer (SITC) 41st Annual Meeting

WALTHAM, Mass., Oct. 26, 2026 (GLOBE NEWSWIRE) -- Xilio Therapeutics, Inc. (Nasdaq: XLO), a clinical-stage biotechnology company discovering and developing masked immuno-oncology therapies for people living with cancer, today announced that the first patient has been dosed in its Phase 1/2 clinical trial evaluating XTX501, a PD-1/masked IL-2 (alpha-optimized) bispecific antibody fusion protein, in patients with metastatic non-small cell lung cancer (NSCLC) who have previously received anti-PD(L)-1 therapy. Xilio also plans to present a trial-in-progress poster for XTX501 at the upcoming SITC Annual Meeting, highlighting the design of the Phase 1/2 clinical trial.

"By combining tumor-selective activation of high potency, alpha-optimized IL-2 and inhibition of PD-1/PD-L1 into a single molecule, XTX501 has the potential to become a foundational backbone immunotherapy regimen in both monotherapy and combination settings," said René Russo, Pharm.D., president and chief executive officer of Xilio. "We believe incorporating masking uniquely positions XTX501 to simultaneously leverage these validated mechanisms to enable precise delivery of high potency IL-2 while minimizing the toxicities observed with non-masked IL-2 therapies. Dosing the first patient with XTX501 marks an important milestone for this program, and we anticipate reporting initial Phase 1 data in metastatic NSCLC in the fourth quarter of 2027."

"PD-1 bispecifics pair a proven checkpoint target with a second, complementary mechanism that can improve depth and duration of anti-tumor immune response, representing one of the most promising new approaches in immuno-oncology," said Yariv J. Houvras, M.D., Ph.D., chief medical officer. "IL-2 is a powerful driver of T cell expansion, and recent data for treatment with a PD-1/non-masked IL-2 have provided clinical validation of these complementary mechanisms, including in patients whose tumors have stopped responding to first-generation checkpoint inhibitors. By leveraging our clinically-validated masking technology, we believe XTX501 is uniquely positioned to deliver potent, tumor-selective immune activation while overcoming the toxicity and rapid clearance that have limited non-masked IL-2 therapies."

Poster Presentation at SITC

Xilio plans to present a trial-in-progress poster at the Society for Immunotherapy of Cancer (SITC) 41st Annual Meeting, taking place from November 4-8, 2026 in Phoenix, Arizona.

Poster presentation details are as follows:

Title: A First-in-Human Phase 1/2 Study of XTX501, a Bispecific PD-1/Masked IL-2, in Metastatic Non-Small Cell Lung Cancer (NSCLC)

Abstract Number: 542

Presentation Date: Saturday, November 7, 2026

Location: Phoenix Convention Center, North Building, Lower Level: Exhibition Halls 4-5-6

About XTX501 and the Phase 1/2 Clinical Trial

XTX501 is a novel, investigational PD-1/masked IL-2 (alpha-optimized) bispecific antibody fusion protein that combines two complementary mechanisms in a single molecule: selective inhibition of the PD-1/PD-L1 pathway and potent IL-2-driven expansion of T cells. The PD-1 binding arm is designed to selectively direct IL-2 activity to PD-1 positive, antigen-experienced T cells and enhance their function. The IL-2 binding arm incorporates a masked, high potency IL-2 variant with an alpha-optimized receptor binding profile. By leveraging Xilio's proprietary masking technology, XTX501 aims to overcome IL-2 receptor-mediated clearance, peripheral activity and tolerability challenges associated with non-masked IL-2 therapies.

Xilio is initially evaluating the safety and tolerability of XTX501 as a monotherapy in patients with metastatic non-small cell lung cancer (NSCLC) and select advanced solid tumors who have previously received anti-PD(L)-1 therapy. The first-in-human, multi-center, open-label Phase 1/2 clinical trial is enrolling patients at multiple sites in the United States. For additional details, please refer to [www.clinicaltrials.gov](https://www.clinicaltrials.gov/ct2/show/study?term=XTX501&rank=1) (identifier: NCT07688577).

Xilio plans to report initial Phase 1 data in patients with metastatic NSCLC in the fourth quarter of 2027.

About Xilio Therapeutics

Xilio Therapeutics is a clinical-stage biotechnology company discovering and developing masked immuno-oncology (I-O) therapies with the goal of significantly improving outcomes for people living with cancer without the systemic side effects of current I-O treatments. Leveraging our clinically-validated masking technology and capabilities, Xilio is developing I-O therapies designed to selectively activate within the tumor microenvironment to achieve durable efficacy without the severe side effects associated with systemically active I-O agents. Learn more by visiting www.xiliotx.com and follow us on LinkedIn ([Xilio Therapeutics, Inc.](https://www.linkedin.com/company/xilio-therapeutics)).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of applicable securities laws and regulations, including, without limitation, statements regarding the potential of XTX501 to become a foundational backbone immunotherapy regimen for solid tumors in both monotherapy and combination settings; Xilio's plans to report initial Phase 1 data in metastatic NSCLC in the fourth quarter of 2027; Xilio's plans to present a trial-in-progress poster for XTX501 at the upcoming SITC Annual Meeting highlighting the design of the Phase 1/2 clinical trial; and Xilio's strategy, goals, business plans and focus. The words "aim," "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of important risks, uncertainties and other factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks related to general market conditions and geopolitical uncertainties; risks and uncertainties related to ongoing and planned research and development activities, including initiating, conducting or completing preclinical studies and clinical trials and the timing and results of such preclinical studies or clinical trials; the delay of any current or planned preclinical studies or clinical trials or the development of Xilio's current or future product candidates; Xilio's ability to obtain and maintain sufficient preclinical and clinical supply of current or future product candidates; initial, preliminary, interim or retrospective preclinical or clinical data or results may not be replicated in or predictive of future preclinical or clinical data or results; Xilio's ability to successfully demonstrate the safety and efficacy of its product candidates and gain approval of its product candidates on a timely basis, if at all; results from preclinical studies or clinical trials for Xilio's product candidates may not support further development of such product candidates; actions of regulatory agencies may affect the initiation, timing and progress of current or future clinical trials; Xilio's ability to obtain, maintain and enforce patent and other intellectual property protection for current or future product candidates; Xilio's need to obtain additional cash resources to advance its pipeline of masked I-O molecules; the impact of international trade policies on Xilio's business, including U.S. and China trade policies; and Xilio's ability to maintain its collaboration and license agreements with AbbVie and Gilead. These and other risks and uncertainties are described in greater detail in the sections entitled "Risk Factor Summary" and "Risk Factors" in Xilio's filings with the U.S. Securities and Exchange Commission (SEC), including Xilio's most recent Quarterly Report on Form 10-Q and any other filings that Xilio has made or may make with the SEC in the future. Any forward-looking statements contained in this press release represent Xilio's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Xilio explicitly disclaims any obligation to update any forward-looking statements.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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