# Xilio Therapeutics Announces Pipeline and Business Updates and Fourth Quarter and Full Year 2024 Financial Results

March 11, 2025

*Additional Phase 2 data for vilastobart, a tumor-activated, Fc-enhanced anti-CTLA-4, in combination with atezolizumab in patients with MSS CRC anticipated in the middle of 2025*

*Advancing masked T cell engager programs in novel ATACR and SEECR formats for PSMA, CLDN18.2 and STEAP1*

*Announced collaboration with AbbVie in the first quarter of 2025 to develop novel tumor-activated, antibody-based immunotherapies, including masked T cell engagers*

WALTHAM, Mass., March 11, 2025 (GLOBE NEWSWIRE) -- Xilio Therapeutics, Inc. (Nasdaq: XLO), a clinical-stage biotechnology company discovering and developing tumor-activated immuno-oncology therapies for people living with cancer, today announced pipeline progress and business updates and reported financial results for the fourth quarter and full year ended December 31, 2024.

"We started 2025 with multiple promising updates across our pipeline, including encouraging initial Phase 2 combination data for vilastobart, our tumor-activated anti-CTLA-4, in patients with late-line MSS CRC, a difficult to treat, immunologically cold tumor type that is increasing in incidence, particularly in younger people," said René Russo, Pharm.D., president and chief executive officer of Xilio. "These data included a preliminary 27% objective response rate in patients without liver metastases and continue to support a differentiated safety profile, including a low incidence of immune-related adverse events and only 5% of patients reporting colitis. We look forward to reporting additional data from the ongoing Phase 2 trial in the middle of this year."

Dr. Russo added, "In addition, we are excited to be advancing multiple novel masked T cell engager programs internally and as part of our recently announced collaboration with AbbVie. Each of these programs leverages our clinically-validated, tumor-activation technology, which we believe has great potential to enhance the activity and tolerability of T cell engagers and open up promising new targets within this class of immunotherapies."

**Pipeline and Business Updates**

***Vilastobart: tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4***

Vilastobart is an investigational tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4 monoclonal antibody designed to block CTLA-4 and deplete regulatory T cells when activated in the tumor microenvironment (TME).

- In January 2025, Xilio announced encouraging initial data from its ongoing Phase 2 clinical trial evaluating vilastobart at a dose of 100 mg once every six weeks (Q6W) in combination with atezolizumab (Tecentriq®) at 1200 mg once every three weeks (Q3W) in patients with metastatic microsatellite stable colorectal cancer (MSS CRC). As of a data cutoff date of January 13, 2025, these data demonstrated a preliminary 27% objective response rate in patients without liver metastases, and responses were accompanied by decreases in levels of serum tumor biomarkers (carcinoembryonic antigen and circulating tumor DNA) as well as improvement in clinical symptoms. In addition, as of the data cutoff date, the combination was generally well-tolerated, with patients experiencing a low incidence of immune-related adverse events and only 5% of patients reporting colitis. These safety data continue to support the potential for vilastobart to be a differentiated next-generation anti-CTLA-4 in combination with PD-(L)1 inhibitors. For more information, read the press release here.

- Xilio expects to report updated data from the Phase 2 clinical trial in the middle of 2025, including additional response assessments and follow-up. In addition, Xilio continues to enroll patients in Phase 1C (combination dose escalation) evaluating vilastobart at the 150 mg Q6W dose level in combination with atezolizumab at 1200 mg Q3W.

- Based on the promising initial Phase 2 proof-of-concept data, Xilio plans to seek opportunities for partnering to accelerate and expand further development of vilastobart.

***XTX301: tumor-activated IL-12***

XTX301 is an investigational tumor-activated IL-12 designed to potently stimulate anti-tumor immunity and reprogram the TME of poorly immunogenic "cold" tumors towards an inflamed or "hot" state. In March 2024, Xilio entered into an exclusive license agreement with Gilead Sciences, Inc. (Gilead) related to Xilio's tumor-activated IL-12 program, including XTX301.

- In December 2024, Xilio announced preliminary data from its ongoing Phase 1 clinical trial of XTX301 in patients with

advanced solid tumors. As of the data cutoff date of November 25, 2024, XTX301 was generally well-tolerated, and no patients experienced a dose limiting toxicity or a dose reduction due to a treatment-related adverse event. In addition, XTX301 showed evidence of sustained interferon gamma signaling without evidence of tachyphylaxis throughout treatment cycles. Tachyphylaxis has historically limited other IL-12 agents. For more information, read the press release here.

- A maximum tolerated dose has not yet been established, and Xilio continues to enroll patients in Phase 1A monotherapy dose escalation and Phase 1B monotherapy dose expansion of the ongoing Phase 1 clinical trial of XTX301.

***XTX501: masked PD-1/IL-2 bispecific***

XTX501 is a novel, tumor-activated bispecific PD-1/IL-2 designed to selectively stimulate PD-1 positive, antigen-experienced T cells and enhance their function. XTX501 incorporates masking designed to overcome IL-2 receptor-mediated clearance and peripheral activity. In preclinical studies, XTX501 demonstrated robust monotherapy activity (including in settings insensitive to PD-1) and tumor-selective pharmacodynamics consistent with its intended mechanism of action. Xilio is currently advancing XTX501 in investigational new drug (IND) application enabling studies and plans to submit an IND application for XTX501 in the middle of 2026.

***Masked T Cell Engager Programs***

Xilio is leveraging its proprietary, clinically-validated tumor-activation platform to advance multiple preclinical programs for masked T cell engagers, including wholly-owned programs targeting the tumor-associated antigens for PSMA, CLDN18.2 and STEAP1 and an additional program in collaboration with AbbVie.

Xilio's masked T cell engager programs include bispecific molecules designed using its advanced tumor-activated cell engager (ATACR) format, which consists of a T cell engager with a masked CD3 targeting domain, and tri-specific molecules designed using its selective effector-enhanced cell engager (SEECR) format. The SEECR format builds upon the ATACR format by adding co-stimulatory signaling designed to further enhance potency and T cell activation.

- PSMA has demonstrated potential as a T cell engager target for prostate cancer. Xilio anticipates nominating a development candidate for its PSMA program in the ATACR format in the third quarter of 2025 and submitting an IND application in the first quarter of 2027.

- CLDN18.2 has broad potential as a T cell engager target for gastric, pancreatic, esophageal and lung cancers. Xilio anticipates nominating a development candidate for its CLDN18.2 program in the ATACR format in the fourth quarter of 2025 and submitting an IND application in the second quarter of 2027.

- STEAP1 has broad potential as a T cell engager target for prostate, colorectal and lung cancers. Xilio anticipates nominating a development candidate for its STEAP1 program in the SEECR format in the first half of 2026 and submitting an IND application in the second half of 2027.

**Corporate Updates**

- In February 2025, Xilio announced a collaboration, license and option agreement with AbbVie leveraging Xilio's proprietary tumor-activation technology and platform to discover and develop novel tumor-activated immunotherapies, including masked T cell engagers. In the first quarter of 2025, Xilio received $52.0 million in upfront payments from AbbVie, including a $10.0 million equity investment, and Xilio will be eligible to receive up to approximately $2.1 billion in total contingent payments for option-related fees and milestones plus tiered royalties. For more information, read the joint press release here.

- In December 2024, Xilio announced the appointment of Caroline Hensley as chief legal officer.

**Year-End and Fourth Quarter 2024 Financial Results**

- **Cash Position:** Cash and cash equivalents were $55.3 million as of December 31, 2024, compared to $44.7 million as of December 31, 2023. In the first quarter of 2025, Xilio received $52.0 million in upfront payments in connection with the collaboration agreement with AbbVie.

- **License Revenue:** License revenue was $1.7 million for the quarter ended December 31, 2024, and $6.3 million for the year ended December 31, 2024, which consisted of revenue recognized under the license agreement and stock purchase agreement with Gilead. No license revenue was recognized for the quarter and year ended December 31, 2023.

- **Research & Development (R&D) Expenses:** R&D expenses were $8.8 million for the quarter ended December 31, 2024, compared to $11.7 million for the quarter ended December 31, 2023. R&D expenses were $41.2 million for the year ended December 31, 2024, compared to $52.1 million for the year ended December 31, 2023. The year-over-year decrease was primarily driven by decreased clinical development activities for XTX202, a masked IL-2, as a result of discontinuing further investment in XTX202, decreased spending related to early-stage programs and indirect research and development costs,

decreased personnel-related costs and decreased manufacturing costs for XTX301, partially offset by increased clinical development activities for vilastobart and XTX301.

- **General & Administrative (G&A) Expenses:** G&A expenses were $6.5 million for the quarter ended December 31, 2024, compared to $6.4 million for the quarter ended December 31, 2023. G&A expenses were $24.8 million for the year ended December 31, 2024, compared to $27.0 million for the year ended December 31, 2023. The year-over-year decrease was primarily driven by decreases in personnel-related costs, professional and consulting fees and directors' and officers' liability insurance, partially offset by an increase in legal fees.

- **Net Loss:** Net loss was $13.1 million for the quarter ended December 31, 2024, compared to $17.7 million for the quarter ended December 31, 2023. Net loss was $58.2 million for the year ended December 31, 2024, compared to $76.4 million for the year ended December 31, 2023.

**Financial Guidance**

Based on its current operating plans, Xilio anticipates that its cash and cash equivalents as of December 31, 2024, together with the $52.0 million in upfront payments received in the first quarter of 2025 in connection with the collaboration agreement with AbbVie, will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2026.

**About Vilastobart and the Phase 1/2 Combination Clinical Trial**

Vilastobart is an investigational tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4 monoclonal antibody designed to block CTLA-4 and deplete regulatory T cells when activated in the tumor microenvironment (TME). In 2023, Xilio entered into a co-funded clinical trial collaboration with Roche to evaluate vilastobart in combination with atezolizumab (Tecentriq®) in a multi-center, open-label Phase 1/2 clinical trial. Xilio is currently evaluating the safety of the combination in Phase 1C dose escalation in patients with advanced solid tumors and the safety and efficacy of the combination in Phase 2 in patients with metastatic microsatellite stable colorectal cancer with and without liver metastases. Please refer to NCT04896697 on www.clinicaltrials.gov for additional details.

**About XTX301 and the Phase 1 Clinical Trial**

XTX301 is an investigational masked IL-12 designed to potently stimulate anti-tumor immunity and reprogram the tumor microenvironment (TME) of poorly immunogenic "cold" tumors towards an inflamed or "hot" state. In March 2024, Xilio entered into an exclusive license agreement with Gilead Sciences, Inc. for Xilio's tumor-activated IL-12 program, including XTX301. Xilio is currently evaluating the safety and tolerability of XTX301 as a monotherapy in patients with advanced solid tumors in a first-in-human, multi-center, open-label Phase 1 clinical trial. Please refer to NCT05684965 on www.clinicaltrials.gov for additional details.

**About Xilio Therapeutics**

Xilio Therapeutics is a clinical-stage biotechnology company discovering and developing tumor-activated, or 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. The company is leveraging its proprietary platform to advance a pipeline of novel, tumor-activated I-O molecules that are designed to optimize the therapeutic index by localizing anti-tumor activity within the tumor microenvironment. Learn more by visiting www.xiliotx.com and follow us on LinkedIn (Xilio Therapeutics, Inc.).

**Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding plans, expectations, development timelines and anticipated milestones for Xilio's programs; the receipt of future contingent payments under Xilio's collaboration or partnership agreements with Roche, Gilead and AbbVie; the potential benefits of any of Xilio's current or future product candidates in any indication; the sufficiency of, and the period in which Xilio expects to have, cash to fund its operations, capital expenditure requirements, and development plans and milestones; and Xilio's strategy, goals and anticipated financial performance, milestones, 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; Xilio's ability to advance multiple early-stage masked T cell engager programs; initial, preliminary or interim 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 fund its operations beyond the first quarter of 2026, including to advance its pipeline of tumor-activated 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 or partnership agreements with Roche, Gilead and AbbVie. 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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**XILIO THERAPEUTICS, INC.**
**Condensed Consolidated Balance Sheets**
**(In thousands)**
**(Unaudited)**

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 55,291 | $ 44,704 |
| Other assets | 15,784 | 16,222 |
| Total assets | $ 71,075 | $ 60,926 |
| **Liabilities and Stockholders' Equity** | | |
| Liabilities | | |
| Deferred revenue | $ 32,780 | $ — |
| Other liabilities | 20,697 | 24,099 |
| Total liabilities | $ 53,477 | $ 24,099 |
| Stockholders' equity | 17,598 | 36,827 |
| Total liabilities and stockholders' equity | $ 71,075 | $ 60,926 |

**XILIO THERAPEUTICS, INC.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**(In thousands, except share and per share data)**
**(Unaudited)**

| | Three Months Ended December 31, | | Years Ended December 31, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| License revenue | $ 1,724 | $ — | $ 6,344 | $ — |
| Operating expenses [1] | | | | |
| Research and development | 8,836 | 11,736 | 41,211 | 52,136 |
| General and administrative | 6,517 | 6,394 | 24,778 | 26,997 |
| Restructuring | — | — | 937 | — |
| Total operating expenses | 15,353 | 18,130 | 66,926 | 79,133 |
| Loss from operations | (13,629) | (18,130) | (60,582) | (79,133) |
| Other income, net | 536 | 475 | 2,341 | 2,729 |
| Net loss and comprehensive loss | $ (13,093) | $ (17,655) | $ (58,241) | $ (76,404) |
| Net loss per share, basic and diluted | $ (0.20) | $ (0.64) | $ (1.09) | $ (2.78) |
| Weighted average common shares outstanding, basic and diluted [2] | 64,675,807 | 27,557,021 | 53,511,424 | 27,496,107 |

(1) Operating expenses include the following amounts of non-cash stock-based compensation expense:

| | Three Months Ended December 31, | | Years Ended December 31, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development expense | $ 377 | $ 519 | $ 1,652 | $ 2,189 |
| General and administrative expense | 1,139 | 1,411 | 4,782 | 5,193 |
| Total stock-based compensation expense | $ 1,516 | $ 1,930 | $ 6,434 | $ 7,382 |

(2) Weighted average common shares outstanding, basic and diluted, includes prefunded warrants to purchase common stock and excludes shares of

restricted common stock that were not vested as of the applicable period.