Xilio Therapeutics Announces Pipeline and Business Updates and First Quarter 2025 Financial Results

May 8, 2025

Updated Phase 2 data to be presented at ASCO for vilastobart, a tumor-activated, Fc-enhanced, anti-CTLA-4, in combination with atezolizumab in patients with metastatic microsatellite stable colorectal cancer (MSS CRC)

Advancing multiple masked T cell engager programs utilizing Xilio's novel ATACR and SEECR formats, with first development candidates anticipated in second half of 2025

WALTHAM, Mass., May 08, 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 first quarter ended March 31, 2025.

"In the first quarter, we presented encouraging initial Phase 2 data for vilastobart, our tumor-activated anti-CTLA-4, in combination with atezolizumab in patients with late-line MSS CRC. These data included a preliminary 27% objective response rate in late-line MSS CRC patients without liver metastases accompanied by a differentiated safety profile with a low incidence of colitis and other immune-related adverse events, which are common dose-limiting adverse events for other CTLA-4 agents," said René Russo, Pharm.D., president and chief executive officer of Xilio. "MSS CRC is an immunologically cold tumor type that is very difficult to treat and increasing in incidence, particularly in younger people for whom no immunotherapy treatment options are currently available. We look forward to reporting updated Phase 2 data at the upcoming ASCO meeting, including additional response assessments and further follow-up on the previously reported data. This quarter was also marked by strong execution across our pipeline, as we continue to advance XTX301, our tumor-activated IL-12, in monotherapy dose escalation in partnership with Gilead, and multiple novel masked T cell engager programs internally and as part of our recently announced collaboration with AbbVie."

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). Vilastobart is currently being evaluated in combination with atezolizumab (Tecentriq®) in Phase 1C combination dose escalation in patients with advanced solid tumors and in a Phase 2 clinical trial in patients with MSS CRC.

- In January 2025, Xilio announced encouraging initial Phase 2 data for vilastobart in combination with atezolizumab in patients with MSS CRC. As of a data cutoff date of January 13, 2025, the combination of vilastobart at 100 mg once every six weeks (Q6W) in combination with atezolizumab at 1200 mg once every three weeks (Q3W) demonstrated a preliminary 27% objective response rate in patients without liver metastases accompanied by a generally well-tolerated safety profile. Patients experienced a low incidence of colitis and other immune-related adverse events, which have historically limited the potential for anti-CTLA-4 therapies. For more information, read the press release here. Based on the promising initial Phase 2 data for vilastobart, Xilio is seeking opportunities to partner the vilastobart program to accelerate and expand further development.

- Xilio plans to report updated data from the ongoing Phase 2 clinical trial in patients with metastatic MSS CRC, including additional response assessments and further follow-up on the previously reported data, at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago from May 30 to June 3, 2025.

  Title: Vilastobart (XTX101), a tumor-activated, Fc-enhanced anti-CTLA-4 monoclonal antibody, in combination with atezolizumab in patients with MSS CRC
  Abstract ID: 3553
  Poster Session: Gastrointestinal Cancer – Colorectal and Anal
  Poster Board: 222
  Session Date and Time: Saturday, May 31, from 9:00 a.m. to 12:00 p.m. CDT

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.

- 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) 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.

- 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. PSMA has demonstrated potential as a T cell engager target for prostate cancer.

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

Corporate Updates

- In the first quarter of 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, and received $52.0 million in total upfront payments from AbbVie. Under the agreement, Xilio is also 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.

First Quarter 2025 Financial Results

- **Cash Position:** Cash and cash equivalents were $89.1 million as of March 31, 2025, compared to $55.3 million as of December 31, 2024. In the first quarter of 2025, Xilio received $52.0 million in total upfront payments in connection with the collaboration agreement with AbbVie.

- **Collaboration and License Revenue:** Collaboration and license revenue was $2.9 million for the quarter ended March 31, 2025, which consisted of $2.9 million of total revenue recognized in connection with the collaborations with AbbVie and Gilead. No collaboration and license revenue was recognized for the quarter ended March 31, 2024.

- **Research & Development (R&D) Expenses:** R&D expenses were $8.3 million for the quarter ended March 31, 2025, compared to $10.4 million for the quarter ended March 31, 2024. The 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 personnel-related costs due to lower headcount and decreased manufacturing costs for XTX301, partially offset by increased spending related to early stage programs and indirect research and development, increased clinical development activities for vilastobart and manufacturing activities for XTX501 in connection with IND-enabling studies.

- **General & Administrative (G&A) Expenses:** G&A expenses were $8.5 million for the quarter ended March 31, 2025, compared to $6.1 million for the quarter ended March 31, 2024. The increase was primarily driven by an increase in legal fees and personnel-related costs, partially offset by a decrease in costs related to directors' and officers' liability insurance.

- **Net Loss:** Net loss was $13.3 million for the quarter ended March 31, 2025, compared to $17.2 million for the quarter ended March 31, 2024.

Financial Guidance

Based on its current operating plans, Xilio anticipates that its cash and cash equivalents as of March 31, 2025 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 timing of data releases; the receipt of future contingent payments under Xilio’s collaboration or partnership agreements with AbbVie and Gilead; the ability to partner vilastobart and expand and accelerate further development; 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 AbbVie, Gilead and Roche. 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 Annual Report on Form 10-K 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.

TECENTRIQ is a registered trademark of Genentech USA, Inc., a member of the Roche Group.

Investor and Media Contact

Scott Young
Vice President, Investor Relations and Corporate Communications
investors@xiliotx.com

XILIO THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands)

(Unaudited)

	March 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 89,073	$ 55,291
Other assets	14,643	15,784
Total assets	$ 103,716	$ 71,075
Liabilities and Stockholders' Equity		
Liabilities		
Deferred revenue	$ 78,994	$ 32,780
Other liabilities	14,022	20,697
Total liabilities	$ 93,016	$ 53,477
Stockholders' equity	10,700	17,598
Total liabilities and stockholders' equity	$ 103,716	$ 71,075

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

	Three Months Ended March 31,	
	2025	2024
Collaboration and license revenue	$ 2,930	$ —
Operating expenses [1]		
Research and development	8,266	10,400
General and administrative	8,515	6,139
Restructuring	—	948
Total operating expenses	16,781	17,487
Loss from operations	(13,851)	(17,487)
Other income, net	586	284
Net loss and comprehensive loss	$ (13,265)	$ (17,203)
Net loss per share, basic and diluted	$ (0.18)	$ (0.62)
Weighted average common shares outstanding, basic and diluted [2]	74,700,364	27,912,584

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

	Three Months Ended March 31,	
	2025	2024
Research and development expense	$ 389	$ 506
General and administrative expense	1,146	1,327
Total stock-based compensation expense	$ 1,535	$ 1,833

(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.