Xilio Therapeutics Announces Pipeline and Business Updates and Third Quarter 2024 Financial Results

November 7, 2024

Will present initial Phase 1C dose escalation data for vilastobart (XTX101), a tumor-activated, Fc-enhanced anti-CTLA-4, in combination with atezolizumab, in a late-breaker poster presentation at the SITC Annual Meeting

Expect to report initial Phase 2 data in microsatellite stable colorectal cancer (MSS CRC) for vilastobart in combination with atezolizumab in the fourth quarter of 2024

Expect to report Phase 1 data for XTX301, a tumor-activated IL-12, in the fourth quarter of 2024

WALTHAM, Mass., Nov. 07, 2024 (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 third quarter ended September 30, 2024.

“Throughout the third quarter, our team continued to drive execution across all stages of our pipeline, including advancing our clinical development programs for vilastobart, a tumor-activated, Fc-enhanced anti-CTLA-4, and XTX301, a tumor-activated IL-12, toward key data milestones and potential value inflection points,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “We look forward to sharing initial data from our Phase 1C dose escalation trial of vilastobart in combination with atezolizumab as part of a late-breaker poster presentation at the SITC Annual Meeting. In addition, we continue to advance multiple promising research-stage programs, including XTX501, our tumor-activated PD-1/IL-2, and tumor-activated immune cell engagers.”

Pipeline and Business Updates

Vilastobart (XTX101): tumor-activated anti-CTLA-4

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

- Xilio will present initial Phase 1C dose escalation data for vilastobart in combination with atezolizumab in a late-breaker poster presentation at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting taking place in Houston, Texas, from November 6-10, 2024.
- In addition, Xilio continues to enroll patients in its ongoing Phase 2 clinical trial evaluating vilastobart in combination with atezolizumab in patients with metastatic MSS CRC, including patients with and without liver metastases.
- Xilio expects to report initial Phase 2 data for vilastobart in combination with atezolizumab in approximately 20 patients with MSS CRC in the fourth quarter of 2024 and in a total of approximately 40 patients with MSS CRC in the first quarter of 2025.

XTX301: tumor-activated, engineered IL-12

XTX301 is an investigational tumor-activated, engineered IL-12 molecule designed to potently stimulate anti-tumor immunity and reprogram the TME of poorly immunogenic “cold” tumors towards an inflamed, or “hot,” state.

- Xilio continues to enroll patients in Phase 1A monotherapy dose escalation and Phase 1B monotherapy dose expansion of its ongoing Phase 1 clinical trial of XTX301 in patients with advanced solid tumors.
- Xilio plans to report safety, pharmacokinetic and pharmacodynamic data from the ongoing Phase 1 clinical trial for XTX301 in the fourth quarter of 2024.

Tumor-Activated Bispecific and Immune Cell Engager Programs

Xilio is leveraging its proprietary platform to advance a pipeline of research-stage programs for tumor-activated bispecific and immune cell engager molecules, including tumor-activated immune cell engagers and tumor-activated effector-enhanced immune cell engagers.

- XTX501 is a 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. Xilio is currently advancing initial investigational new drug (IND)-enabling activities for XTX501.
- Xilio will present preclinical data from its tumor-activated SELECTIVE EFFECTOR-ENHANCED CELL ENGAGER (SEECR)

format in a poster session at the SITC Annual Meeting. Details on the poster presentation can be found here.

Third Quarter 2024 Financial Results

- **Cash Position:** Cash and cash equivalents were $61.3 million as of September 30, 2024, compared to $44.7 million as of December 31, 2023.
- **License Revenue:** License revenue was $2.3 million for the quarter ended September 30, 2024, which consisted of revenue recognized under the license agreement and stock purchase agreement with Gilead. No license revenue was recognized for the quarter ended September 30, 2023.
- **Research & Development (R&D) Expenses:** R&D expenses were $10.8 million for the quarter ended September 30, 2024, compared to $11.1 million for the quarter ended September 30, 2023. The decrease was primarily driven by decreased clinical development activities for XTX202, a tumor-activated, IL-2, decreased spending related to early-stage programs and indirect research and development costs and decreased personnel-related costs, partially offset by increased clinical development activities for vilastobart and XTX301.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.3 million for each of the quarters ended September 30, 2024 and September 30, 2023.
- **Net Loss:** Net loss was $14.0 million for the quarter ended September 30, 2024, compared to $16.7 million for the quarter ended September 30, 2023.

Financial Guidance

Based on its current operating plans, Xilio anticipates that its existing cash and cash equivalents as of September 30, 2024, will be sufficient to fund its operating expenses and capital expenditure requirements through the end of the second quarter of 2025.

About Vilastobart (XTX101) 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 tumor-activated 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 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 using its proprietary platform to advance a pipeline of novel, tumor-activated clinical and preclinical I-O molecules that are designed to optimize the therapeutic index by localizing anti-tumor activity within the tumor microenvironment, including tumor-activated cytokines, antibodies, bispecifics and immune cell engagers. 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 and anticipated milestones for vilastobart (XTX101) and XTX301, including plans and timing for reporting clinical data for each of these programs; the potential for Xilio to leverage its research platform to develop tumor-activated bispecific and immune cell engager molecules; Xilio’s plans and expectations for advancing initial IND-enabling activities for XTX501; the potential benefits of any of Xilio’s current or future product candidates in treating patients as a monotherapy or combination therapy; Xilio’s estimated cash and cash equivalents and the period in which Xilio expects to have cash to fund its operations; 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, general market conditions; risks and uncertainties related to ongoing and planned research and development activities, including initiating, conducting or completing preclinical studies, including IND-enabling activities, 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 advancement of multiple early-stage immune cell engager programs, including tumor-activated immune cell engagers and tumor-activated effector-enhanced immune cell engagers; initial, preliminary or interim preclinical or clinical data or results, which 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, which may not support further development of such product candidates; actions of regulatory agencies, which 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 ability to obtain and maintain sufficient cash resources to fund its operations; the impact of international trade policies on Xilio's business, including U.S. and China trade policies; Xilio's ability to maintain its clinical trial collaboration with Roche to develop vilastobart (XTX101) in combination with atezolizumab; and Xilio's ability to maintain its license agreement with Gilead to develop and commercialize XTX301. 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.

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

Xilio 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)

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 61,259	$ 44,704
Other assets	13,399	16,222
Total assets	74,658	60,926
Liabilities and Stockholders' Equity		
Liabilities		
Deferred revenue	34,504	—
Other liabilities	19,180	24,099
Total liabilities	53,684	24,099
Stockholders' equity	20,974	36,827
Total liabilities and stockholders' equity	74,658	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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
License revenue	$ 2,263	$ —	$ 4,620	$ —
Operating expenses [1]				
Research and development	10,759	11,051	32,375	40,400
General and administrative	6,307	6,310	18,261	20,603
Restructuring	(41)	—	937	—
Total operating expenses	17,025	17,361	51,573	61,003
Loss from operations	(14,762)	(17,361)	(46,953)	(61,003)
Other income, net	742	613	1,805	2,254
Net loss and comprehensive loss	$ (14,020)	$ (16,748)	$ (45,148)	$ (58,749)
Net loss per share, basic and diluted	$ (0.22)	$ (0.61)	$ (0.91)	$ (2.14)
Weighted average common shares outstanding, basic and diluted	63,465,063	27,523,821	49,762,800	27,475,579

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expense	$ 384	$ 548	$ 1,275	$ 1,670
General and administrative expense	1,190	1,313	3,643	3,782
Total stock-based compensation expense	$ 1,574	$ 1,861	$ 4,918	$ 5,452