Xilio Therapeutics Announces Pipeline and Business Updates and First Quarter 2023 Financial Results

May 9, 2023

Initiated Phase 2 clinical trial for XTX202, a tumor-activated IL-2

Anticipate reporting preliminary Phase 1 safety, PK, PD, and anti-tumor activity data for XTX101, a tumor-activated, Fc-enhanced anti-CTLA-4, in the second quarter of 2023

Ended first quarter of 2023 with $93.3 million in cash and cash equivalents, with cash runway anticipated into the end of the second quarter of 2024

WALTHAM, Mass., May 09, 2023 (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, 2023.

“In the first quarter, we continued to progress multiple clinical programs, notably with the recent initiation of our first Phase 2 clinical trial,” said René Russo, Pharm.D., chief executive officer of Xilio. “The Phase 2 trial will assess the safety and efficacy of XTX202, our tumor-activated IL-2, in patients with advanced renal cell carcinoma and melanoma. To date, we have administered XTX202 in the outpatient setting at high dose levels and have not observed any of the severe systemic side effects commonly associated with recombinant IL-2. In addition, we plan to report preliminary data later this quarter from our Phase 1 clinical trial for XTX101, our tumor-activated, Fc-enhanced anti-CTLA-4.”

Pipeline and Business Updates

XTX202: tumor-activated, engineered, beta-gamma biased IL-2

XTX202 is an investigational tumor-activated beta-gamma biased, engineered IL-2 molecule designed to potently stimulate CD8+ effector T cells and natural killer (NK) cells without concomitant stimulation of regulatory T cells when activated (unmasked) in the tumor microenvironment (TME). XTX202 is currently being evaluated in an ongoing Phase 1/2 clinical trial in patients with advanced solid tumors.

- Xilio recently initiated patient dosing at an initial dose of 1.4mg/kg in a Phase 2 clinical trial evaluating XTX202 as a monotherapy in patients with unresectable or metastatic melanoma and metastatic renal cell carcinoma who have progressed on standard-of-care treatment.
- In addition, Xilio recently cleared the 1.4 mg/kg dose level (dose level five) in monotherapy dose-escalation (Part 1A) for the Phase 1 clinical trial and is currently dosing patients at the 2.8 mg/kg dose level (dose level six).
- A maximum tolerated dose has not yet been determined, and enrollment in Part 1A and Part 1B of the Phase 1 clinical trial is ongoing.
- Xilio anticipates reporting preliminary anti-tumor activity, safety, pharmacokinetic (PK) and pharmacodynamic (PD) data from the Phase 1/2 clinical trial in the third quarter of 2023. The company anticipates the reported data will include approximately 15-20 evaluable patients across a range of solid tumors treated at the 1 mg/kg dose or higher across all cohorts in the Phase 1/2 clinical trial.

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 has opened clinical trial sites and is actively screening patients for enrollment at a starting dose of 5.0 ug/kg (0.005 mg/kg) in monotherapy dose-escalation for its Phase 1 clinical trial evaluating the safety and tolerability of XTX301 in patients with advanced solid tumors.
- Xilio anticipates reporting preliminary safety data from the Phase 1 clinical trial into at least the third dose level in the fourth quarter of 2023.

XTX101: tumor-activated, Fc-enhanced anti-CTLA-4

XTX101, an investigational tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4, is currently being evaluated in monotherapy dose-expansion (Part 1B) of an ongoing Phase 1 clinical trial in patients with advanced solid tumors.

- Xilio today announced the acceptance of an abstract highlighting preliminary Phase 1 data at the 2023 American Society of

Clinical Oncology (ASCO) Annual Meeting. Xilio plans to report additional preliminary Phase 1 safety, PK, PD, and anti-tumor activity data by the end of the second quarter of 2023.
- In addition, as previously announced, Xilio plans to continue to explore strategic opportunities to advance XTX101 with a partner beyond the current Phase 1 trial.

Upcoming Presentations and Accepted Abstracts

Xilio today announced the acceptance of the following two abstracts at the 2023 ASCO Annual Meeting in Chicago, Illinois.

Xilio will present a trials-in-progress poster highlighting details of the Phase 1 clinical trial for XTX301:

- **Presentation title:** A first-in-human study of XTX301, a masked, tumor-activated interleukin-12 (IL-12), in patients with advanced solid tumors.
- **Session date and time:** June 3, 2023, 9:00 am to 12:00 pm EDT
- **Abstract number:** TPS2672

The following abstract highlighting preliminary safety, PK, and anti-tumor activity data from the Phase 1 clinical trial for XTX101 was accepted for inclusion in the 2023 ASCO Annual Meeting Proceedings, *Journal of Clinical Oncology* supplement:

- **Presentation Title:** Phase 1/2 study of XTX101, a masked, tumor-selective Fc-modified anti-CTLA-4, in patients with advanced solid tumors.
- **Abstract number:** e14685

First Quarter 2023 Financial Results

- **Cash Position:** Cash and cash equivalents were $93.3 million as of March 31, 2023, compared to $120.4 million as of December 31, 2022.
- **Research & Development (R&D) Expenses:** R&D expenses were $16.1 million for the quarter ended March 31, 2023, compared to $14.9 million for the quarter ended March 31, 2022. The increase was primarily driven by increased clinical development activities for XTX202, increased clinical development and manufacturing activities for XTX301, increased personnel-related costs, and increased costs related to the company's earlier-stage programs. These increases were partially offset by decreases in manufacturing activities for XTX202, preclinical development activities for XTX301 and clinical development activities for XTX101.
- **General & Administrative (G&A) Expenses:** G&A expenses were $7.4 million for the quarter ended March 31, 2023, compared to $6.3 million for the quarter ended and March 31, 2022. The increase was primarily driven by increased personnel-related costs and an increase in professional and consulting fees.
- **Net Loss:** Net loss was $22.6 million for the quarter ended March 31, 2023, compared to $21.4 million for the quarter ended March 31, 2022.

Financial Guidance

Xilio anticipates that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the end of the second quarter of 2024.

About XTX202 (IL-2) and the Phase 1/2 Clinical Trial

XTX202 is an investigational tumor-activated beta-gamma biased, engineered IL-2 molecule designed to potently stimulate CD8+ effector T cells and natural killer (NK) cells without concomitant stimulation of regulatory T cells when activated (unmasked) in the tumor microenvironment (TME). The Phase 1 clinical trial for XTX202 is a first-in-human, multi-center, open-label trial designed to evaluate the safety and tolerability of XTX202 as a monotherapy in patients with advanced solid tumors. The Phase 2 clinical trial for XTX202 is a multi-center, open-label trial designed to evaluate the safety and efficacy of XTX202 as a monotherapy in patients with unresectable or metastatic melanoma and metastatic renal cell carcinoma who have progressed on standard-of-care treatment. Please refer to NCT05052268 on www.clinicaltrials.gov for additional details.

About XTX301 (IL-12) and the Phase 1 Clinical Trial

XTX301 is an investigational tumor-activated, engineered IL-12 molecule designed to potently stimulate anti-tumor immunity and reprogram the tumor microenvironment (TME) of poorly immunogenic "cold" tumors towards an inflamed or "hot" state. The Phase 1 clinical trial for XTX301 is a first-in-human, multi-center, open-label trial designed to evaluate the safety and tolerability of XTX301 as a monotherapy in patients with advanced solid tumors. Please refer to NCT05684965 on www.clinicaltrials.gov for additional details.

About XTX101 (anti-CTLA-4) and the Phase 1 Clinical Trial

XTX101 is an investigational tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4 monoclonal antibody designed to deplete regulatory T cells when activated (unmasked) in the tumor microenvironment (TME). The Phase 1 clinical trial is a first-in-human, multi-center, open-label trial designed to evaluate the safety and tolerability of XTX101 for the treatment of adult patients with advanced solid tumors. Please refer to NCT04896697 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 geographically precise solutions (GPS) platform to build a pipeline of novel, tumor-activated molecules, including cytokines and other biologics, which are designed to optimize their therapeutic index and localize anti-tumor activity within the tumor microenvironment. Xilio is currently advancing multiple programs for tumor-activated I-O treatments in clinical development, as well as programs in preclinical development. Learn more by visiting www.xiliotx.com and follow us on Twitter (@xiliotx) and 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, timing and expectations related to reporting preliminary data from the Phase 1/2 clinical trial for XTX202, including the anticipated number of patients treated at the 1 mg/kg dose level or higher; reporting preliminary safety data from the Phase 1 clinical trial for XTX301; reporting preliminary data from the Phase 1 clinical trial for XTX101; potential collaborations to advance XTX101; the potential benefits of any of Xilio's current or future product candidates in treating patients; Xilio's ability to fund its operating expenses and capital expenditure requirements with its existing cash and cash equivalents; 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 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 advancement of multiple early-stage programs; there can be no assurance that interim or preliminary preclinical or clinical data or results will be 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 current or future operating expenses and capital expenditure requirements; the impact of international trade policies on Xilio's business, including U.S. and China trade policies; and Xilio's ability to seek, establish and maintain a collaboration or partnership to develop XTX101 with a collaborator or partner. 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.

For Investor Inquiries:

Melissa Forst
Argot Partners
Xilio@argotpartners.com

For Media Inquiries:

Julissa Viana
Vice President, Corporate Communications
media@xiliotx.com

XILIO THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 93,271	$ 120,385
Other assets	18,234	18,780
Total assets	$ 111,505	$ 139,165
Liabilities and Stockholders' Equity		
Liabilities	$ 26,713	$ 33,518
Stockholders' equity	84,792	105,647
Total liabilities and stockholders' equity	$ 111,505	$ 139,165

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,	
	2023	**2022**
Operating expenses[(1)]		
Research and development	$ 16,131	$ 14,920
General and administrative	7,395	6,304
Total operating expenses	23,526	21,224
Loss from operations	(23,526)	(21,224)
Other income (expense), net		
Other income (expense), net	880	(129)
Total other income (expense), net	880	(129)
Net loss and comprehensive loss	$ (22,646)	$ (21,353)
Net loss per share, basic and diluted	$ (0.83)	$ (0.78)
Weighted average common shares outstanding, basic and diluted	27,433,252	27,367,377

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

	Three Months Ended March 31,	
	2023	**2022**
Research and development expense	$ 573	$ 596
General and administrative expense	1,218	1,433
Total stock-based compensation expense	$ 1,791	$ 2,029