Xilio Therapeutics Announces $11.3 Million Private Placement Equity Financing

March 28, 2024

Announces strategic portfolio reprioritization focused on rapid advancement of clinical-stage programs for XTX301, a tumor-activated, IL-12, and XTX101, a tumor-activated, Fc-enhanced anti-CTLA-4, and leveraging the company's promising research platform for tumor-activated bispecific and cell engager molecules

Reports additional Phase 2 data for XTX202, a tumor-activated, beta-gamma biased IL-2, supporting potential as combination therapy; plans to discontinue monotherapy development and evaluate collaboration opportunities to advance development

Anticipates cash runway into Q2 2025

Xilio to host conference call today at 8:00 a.m. ET

WALTHAM, Mass., March 28, 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 that it has entered into a securities purchase agreement with certain existing accredited investors, including Bain Capital Life Sciences and Rock Springs Capital, to issue and sell an aggregate of 1,953,125 shares of Xilio common stock at a price of $0.64 per share and prefunded warrants to purchase up to an aggregate of 15,627,441 shares of Xilio common stock at a purchase price of $0.6399 per prefunded warrant share, through a private investment in public equity financing. The prefunded warrants will have an exercise price of $0.0001 per share of common stock, be immediately exercisable and remain exercisable until exercised in full. Xilio anticipates receiving aggregate gross proceeds from the private placement of approximately $11.3 million, before deducting placement agent fees and expenses payable by the company. The private placement is expected to close on April 2, 2024, subject to the satisfaction of customary closing conditions. Xilio expects to use the proceeds from the private placement to fund working capital and other general corporate purposes.

"Together with our partnership announced with Gilead today for XTX301, our tumor-activated IL-12, this financing enables us to prioritize clinical development for XTX301 as well as XTX101, our tumor-activated, Fc-enhanced anti-CTLA-4, while making focused investments in our promising research-stage pipeline for tumor-activated bispecific and cell engager molecules," said René Russo, Pharm.D., president and chief executive officer of Xilio. "We are grateful for our investors' confidence in the potential of our pipeline and platform to develop tumor-activated immuno-oncology therapies for people living with cancer."

Dr. Russo continued, "We believe our decision to reprioritize Xilio's clinical- and research-stage investments and resources best positions us to achieve near-term clinical milestones and value-drivers while seeking to deliver on the long-term promise of our differentiated research platform and capabilities. I extend sincere gratitude to each employee impacted by this difficult decision, as their contributions and dedication have played a critical role in working toward Xilio's mission to improve the lives of patients with cancer."

Exclusive License Agreement with Gilead

As previously announced today, Xilio entered into an exclusive license agreement with Gilead Sciences, Inc. (Gilead) for Xilio's tumor-activated IL-12 program, including XTX301. Under the terms of the agreement:

- Xilio will receive $43.5 million in upfront payments, including a cash payment of $30.0 million and an initial equity investment by Gilead of $13.5 million in Xilio common stock at a purchase price of $1.97 per share.
- Xilio will be eligible to receive up to $604.0 million in additional contingent payments, including proceeds from up to three additional equity investments by Gilead, a $75.0 million transition fee and specified development, regulatory and sales-based milestones. Xilio will also be eligible to receive tiered royalties ranging from high single digits to mid-teens on annual global net product sales.
- Prior to the potential transition fee, Xilio is eligible to receive up to a total of $29.0 million in additional equity investments and a development milestone payment.
- Xilio will be responsible for conducting clinical development for XTX301 in the ongoing Phase 1 clinical trial through dose expansion. Following the delivery by Xilio of a specified clinical data package for XTX301, Gilead can elect to transition responsibilities for the development and commercialization of XTX301 to Gilead, subject to the terms of the agreement and payment by Gilead of the $75.0 million transition fee. If Gilead elects not to transition responsibilities for development and commercialization of the licensed products and pay the transition fee, then the license agreement will automatically terminate.

For more information on the Gilead transactions, read the press release here.

Additional Data from Phase 2 Clinical Trial for XTX202

Xilio today also announced additional data from its Phase 2 clinical trial evaluating XTX202, a tumor-activated, beta-gamma biased IL-2, in patients with metastatic renal cell carcinoma (RCC) or unresectable or metastatic melanoma.

As of a data cutoff date of March 6, 2024:

- A total of 17 RCC patients and 20 melanoma patients were administered XTX202 in the Phase 2 trial in an outpatient setting at dose levels of 1.4 mg/kg once every three weeks (Q3W) or 4 mg/kg Q3W.
- In 26 patients evaluable for anti-tumor activity at both dose levels, stable disease (SD) continued to be the best response. Investigators reported SD of at least nine-weeks duration in 7 RCC patients (70% disease control rate) and in 9 melanoma patients (56% disease control rate). In addition, XTX202 continued to be generally well-tolerated with safety data consistent with previously reported results. Xilio plans to present the full data set at a future medical meeting.

Together with previously reported data, Xilio believes these additional data further validate the company's tumor-activated approach and support the broad potential for XTX202 as a combination therapy. Xilio plans to explore strategic opportunities to continue to develop XTX202 in combination with other agents.

Strategic Portfolio Reprioritization

In addition, Xilio today announced plans to reprioritize its resources, including a workforce reduction.

As part of the strategic portfolio reprioritization and workforce reduction, Xilio plans to:

- focus on rapidly advancing clinical development for XTX301 and XTX101 and leveraging the company's promising research platform to advance differentiated bispecific and cell engager molecules;
- discontinue further investment in XTX202 as a monotherapy; and
- undertake efforts to further reduce its expenses and streamline its operations, including a reduction in headcount of 15 employees, representing approximately 21% of the company's current workforce.

In connection with the workforce reduction, Xilio expects to incur one-time costs of approximately $1.0 million, primarily related to cash expenditures for severance and benefits continuation. The company estimates that the workforce reduction will be substantially completed in the first half of 2024.

Financial Guidance

In the first quarter of 2024, Xilio repaid all amounts outstanding under its loan and security agreement with Pacific Western Bank (PacWest), and PacWest released all security interests in the company's and its affiliates' assets.

As of December 31, 2023, cash and cash equivalents were $44.7 million. This cash estimate is a preliminary estimate and is based on information available to management as of the date of this private placement, and these estimates could change.

Based on its current operating plans, Xilio anticipates that its cash and cash equivalents as of December 31, 2023, together with the upfront payment under the license agreement with Gilead, the proceeds from the initial equity investment by Gilead, the anticipated net proceeds from the private placement and after giving effect to one-time costs and anticipated future cost savings associated with the strategic portfolio reprioritization and workforce reduction and the repayment of the outstanding loan balance under the PacWest loan agreement in the first quarter of 2024, will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2025.

Conference Call Information

Xilio will host a live webcast today beginning at 8:00 a.m. ET to discuss this financing, the transaction with Gilead and other corporate updates. To access the live call, please register here. A webcast of the call will also be available under "Events and Presentations" in the Investors & Media section of the Xilio website at https://ir.xiliotx.com/. The archived webcast will be available on the Xilio website approximately two hours after the conference call and will be available for 30 days following the call.

Additional Information Regarding the Private Placement

The securities being issued and sold in this private placement, including the shares of common stock underlying the prefunded warrants, are being made in a transaction not involving a public offering and have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements. Concurrently with the execution of the securities purchase agreement, Xilio and the investors entered into a registration rights agreement pursuant to which Xilio has agreed to file a registration statement with the Securities and Exchange Commission registering the resale of the securities sold in the private placement.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction. Any offering of the common stock or prefunded warrants described above under the resale registration statement will only be by means of a prospectus.

About XTX301 (IL-12) 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. 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 XTX101 (anti-CTLA-4) and the Phase 1/2 Combination Clinical Trial

XTX101 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 (unmasked) in the tumor microenvironment (TME). In the third quarter of 2023, Xilio entered into a co-funded clinical trial collaboration with Roche to evaluate XTX101 in combination with atezolizumab (Tecentriq®) in a multi-center, open-label Phase 1/2 clinical trial. Xilio is currently evaluating the safety and tolerability of the combination in patients with advanced solid tumors in the Phase 1 dose escalation portion of the clinical trial. Subject to the results of Phase 1 combination dose escalation, Xilio plans to evaluate the safety and efficacy of the combination in the Phase 2 portion of the clinical trial in patients with microsatellite stable colorectal cancer. Please refer to NCT04896697 on www.clinicaltrials.gov for additional details.

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

XTX202 is an investigational tumor-activated, beta-gamma biased IL-2 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 TME. The Phase 2 clinical trial 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 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 build a pipeline of novel, tumor-activated molecules, including antibodies, cytokines, bispecifics and cell engagers, which are designed to optimize the 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 leveraging its differentiated research platform to advance tumor-activated bispecific and cell engager molecules in preclinical development. 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 the expected closing of the private placement; Xilio's anticipated use of proceeds from the private placement; whether the conditions for the closing of the private placement will be satisfied; the filing of a registration statement to register the resale of the shares and pre-funded warrant shares to be issued and sold in the private placement; the amount of proceeds expected from the transactions with Gilead; the timing and certainty of completion of the transactions with Gilead; expectations related to the cost, savings and timing of the strategic portfolio reprioritization and workforce reduction; the potential impact of the strategic portfolio reprioritization and workforce reduction on Xilio's operations and development timelines; Xilio's intent and ability to explore strategic opportunities to develop XTX202 in combination with other agents; 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; the potential for Xilio to leverage its research platform to develop bispecific or cell engager molecules; 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; whether the conditions for the closing of the transactions with Gilead will be satisfied; whether the conditions for the closing of the private placement will be satisfied; Xilio's ability to successfully achieve the benefits of the strategic portfolio reprioritization and workforce reduction; 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; interim or preliminary 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 XTX101 in combination with atezolizumab; and Xilio's ability to maintain its license agreement with Gilead to develop 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.

Contacts:

Investors:
Melissa Forst
Argot Partners
Xilio@argotpartners.com

Media:
Dan Budwick
1AB
dan@1abmedia.com