Xilio Therapeutics to Present Initial Phase 2 Data for Vilastobart (XTX101), a Tumor-Activated Anti-CTLA-4, in Combination with Atezolizumab in Patients with Metastatic Microsatellite Stable Colorectal Cancer at ASCO GI

December 19, 2024

Announces preliminary Phase 1 data for XTX301, a tumor-activated IL-12, demonstrating an improved tolerability profile over historical data for rhIL-12, with no dose-limiting toxicities

Completed additional private placement with Gilead for purchase of remaining equity investment in connection with XTX301 partnership

WALTHAM, Mass., Dec. 19, 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 plans to present initial data from its ongoing Phase 2 trial for vilastobart (XTX101), a tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4, in combination with atezolizumab (Tecentriq®) in patients with metastatic microsatellite stable colorectal cancer (MSS CRC) at the ASCO Gastrointestinal (ASCO GI) Cancers Symposium in San Francisco, California from January 23-25, 2025. In addition, today the company announced preliminary data from Phase 1 dose escalation for XTX301, an investigational tumor-activated IL-12.

"We are encouraged by the early evidence of responses in patients with cold tumors, including MSS colorectal cancer, reported for the combination of vilastobart and atezolizumab in Phase 1C dose escalation earlier this year, and we look forward to sharing initial Phase 2 data for the combination in MSS CRC at ASCO GI in January," said Katarina Luptakova, M.D., chief medical officer of Xilio. "In addition, the preliminary Phase 1 data we reported today for XTX301, our tumor-activated IL-12, highlight its promising clinical profile, including no dose-limiting toxicities reported to date and consistent interferon gamma signaling observed throughout treatment cycles."

ASCO GI Presentation Details for Vilastobart (anti-CTLA-4)

Xilio will present initial data from its ongoing Phase 2 trial for vilastobart (XTX101), a tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4, in combination with atezolizumab (Tecentriq®) in patients with metastatic MSS CRC:

- **Title:** Phase 1/2 study of XTX101, a tumor-activated, Fc-enhanced anti-CTLA-4 monoclonal antibody, in combination with atezolizumab in patients with advanced solid tumors and in MSS CRC
- **Abstract Number**: 206
- **Presentation Date**: Saturday, January 25, 2025
- **Poster Session C**: Cancers of the Colon, Rectum, and Anus
- **Time:** 7:00 AM-7:55 AM PST
- **Location**: Moscone West, San Francisco, CA

In November 2024, Xilio presented encouraging initial data from the ongoing Phase 1C dose escalation trial for the combination of vilastobart and atezolizumab in patients with advanced solid tumors. For more information, read the press release here.

Preliminary Data from Ongoing Phase 1 Trial for XTX301 (IL-12)

As of the data cutoff date of November 25, 2024, 34 patients with advanced solid tumors had been treated with XTX301 at doses ranging from 5 µg/kg to 60 µg/kg administered once every three weeks (Q3W) or once every six weeks (Q6W). Patients were generally heavily pre-treated, and approximately 68% of patients received three or more prior lines of anti-cancer therapy.

A maximum tolerated dose has not yet been established. 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.

In addition, preliminary results as of the data cutoff date showed:

- Sustained interferon gamma (IFNɣ) signaling without evidence of tachyphylaxis throughout treatment cycles. Tachyphylaxis has historically limited other IL-12 agents.
- Evidence of dose-dependent pharmacology with T cell, natural killer (NK) cell and NKT cell proliferation.
- Consistent with the tumor-activated design of XTX301, no measurable activated XTX301 was detected in peripheral circulation across all dose levels and schedules.
- Across all dose levels and schedules, no Grade 4 or Grade 5 treatment-related adverse events (AEs) were reported by investigators and no patients experienced a dose limiting toxicity or a dose reduction due to a treatment-related AE.
- In addition, across all dose levels and schedules, the majority of treatment-related AEs were Grade 1 or 2 and most

commonly consisted of flu-like symptoms, cytokine release syndrome, increased aspartate aminotransferase (AST) and alanine aminotransferase (ALT) and decreased blood cell counts.

Additional Private Placement with Gilead

On December 18, 2024, Xilio issued and sold an aggregate of approximately $8.2 million in common stock and prefunded warrants to Gilead Sciences, Inc. (Gilead) in an additional private placement pursuant to the stock purchase agreement Xilio entered into with Gilead in March 2024. Upon the closing of the additional private placement, Xilio has issued and sold an aggregate of $25.0 million in common stock and prefunded warrants to Gilead, representing the maximum aggregate investment under the March 2024 stock purchase agreement. After giving effect to the proceeds from the additional private placement with Gilead together with Xilio's existing cash and cash equivalents, Xilio now anticipates that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the third 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 to present initial data from the ongoing Phase 2 trial for vilastobart in combination with atezolizumab in patients with advanced MSS CRC; expectations regarding the clinical profile of XTX301; the period in which Xilio expects to have cash to fund its operations; and Xilio's strategy, goals, 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 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; 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 vilastobart 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.

Investor and Media Contact

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