# Xilio Therapeutics Highlights Recent Advances Across Clinical Pipeline and Encouraging Preliminary Phase 1 Safety Data for XTX301, a Tumor-Activated IL-12, Further Validating the Promise of Its Tumor-Activated Immuno-Oncology Therapies

January 8, 2024

*Dosing XTX301 at 45 ug/kg once every three weeks (dose level 3) in ongoing Phase 1 trial, nearly 100x the maximum tolerated dose of rhIL-12, with no dose-limiting toxicities observed to date*

*Initiated patient dosing in Phase 1/2 trial for XTX101, a tumor-activated, Fc-enhanced anti-CTLA-4, in combination with atezolizumab*

*Based on recently accelerated enrollment, now plan to report Phase 2 trial data for XTX202, a tumor-activated, beta-gamma biased IL-2, at the 4.0 mg/kg dose by end of first quarter of 2024*

WALTHAM, Mass., Jan. 08, 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 highlighted recent advances across its clinical pipeline and reported encouraging preliminary safety data from the first three dose levels in the ongoing Phase 1 trial evaluating XTX301, a tumor-activated IL-12, in patients with advanced solid tumors.

“For more than 20 years, IL-12 development has been relentlessly pursued due to its unique potential to treat immunologically cold tumors. However, treatment with IL-12 has remained out of reach due to the lethal toxicities associated with systemic administration,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “Today we announced that XTX301, our tumor-activated IL-12, has been administered at doses up to 45 ug/kg, which is nearly 100 times the maximum tolerated dose of rhIL-12, with no dose-limiting toxicities observed to date. This is now the third clinical-stage program from the Xilio platform to highlight the potential of our tumor-activated approach.”

Xilio today announced recent advances across its three clinical-stage programs:

***XTX101 (tumor-activated, Fc-enhanced anti-CTLA-4)***

- Xilio recently initiated patient dosing in the Phase 1 dose escalation portion of the Phase 1/2 trial evaluating XTX101 in combination with atezolizumab in patients with advanced solid tumors.
- Subject to obtaining sufficient additional capital, Xilio today reaffirmed plans to:
  - Select a recommended Phase 2 dose for XTX101 in combination with atezolizumab in the second quarter of 2024.
  - Subject to the results of the Phase 1 combination dose escalation portion of the trial, initiate the Phase 2 portion of the trial for XTX101 in combination with atezolizumab in patients with microsatellite stable colorectal cancer (MSS CRC) in the third quarter of 2024.
  - Report initial Phase 2 data for XTX101 in combination with atezolizumab in approximately 20 patients with MSS CRC in the fourth quarter of 2024 and in approximately 20 additional patients (40 patients total) in the first quarter of 2025.

***XTX202 (tumor-activated, beta-gamma biased IL-2)***

- Xilio continues to enroll patients at the 4.0 mg/kg dose in its ongoing Phase 2 monotherapy trial for XTX202 in patients with metastatic renal cell carcinoma or unresectable or metastatic melanoma.
- Based on recently accelerated enrollment, Xilio now plans to report Phase 2 monotherapy data for XTX202 in approximately 20 patients treated at the 4.0 mg/kg dose by the end of the first quarter of 2024.

***XTX301 (tumor-activated IL-12)***

- Xilio today announced encouraging preliminary safety data from its ongoing Phase 1 trial evaluating XTX301 as a monotherapy in dose escalation in patients with advanced solid tumors.

- As of a data cutoff date of January 5, 2024, nine patients had been treated with XTX301 in the outpatient setting in Phase 1 dose escalation at three dose levels ranging from 5 ug/kg to 45 ug/kg administered once every three weeks.

- XTX301 was generally well-tolerated across all dose levels with no dose-limiting toxicities observed in patients as of the data cutoff date.

- Subject to obtaining sufficient additional capital, Xilio today reaffirmed plans to report Phase 1 safety, pharmacokinetic and pharmacodynamic data for XTX301 in patients with advanced solid tumors in the second half of 2024.

**Financial Guidance**

Xilio continues to anticipate 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 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 obtaining sufficient additional capital and 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 (MSS CRC). 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 tumor microenvironment (TME). Xilio is currently evaluating 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 in a multi-center, open-label Phase 2 clinical trial. 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 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 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 antibodies, 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 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 report Phase 2 monotherapy data for XTX202; additional plans and anticipated milestones for XTX101, XTX202 and XTX301, subject to obtaining sufficient additional capital; the potential benefits of any of Xilio’s current or future product candidates in treating patients as a monotherapy or combination therapy; 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, 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 until and beyond the end of the second quarter of 2024; the impact of international trade policies on Xilio’s business, including U.S. and China trade policies; and Xilio’s ability to maintain its clinical trial collaboration with Roche to develop XTX101 in combination with atezolizumab. 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.

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**Contacts:**


Investors:
Melissa Forst
Argot Partners
Xilio@argotpartners.com

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