Xilio Therapeutics Announces Multiple Masked T Cell Engager Programs

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Also entered into collaboration and option agreement with AbbVie to develop novel tumor-activated immunotherapies, including masked T cell engagers, with $52.0 million in upfront payments

Extended anticipated cash runway into the first quarter of 2026

Company to host investor conference call and webcast today at 8:30 am ET

WALTHAM, Mass., Feb. 12, 2025 (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 three wholly-owned preclinical programs for masked T cell engagers targeting prostate-specific membrane antigen (PSMA), claudin 18.2 (CLDN18.2) and six-transmembrane epithelial antigen of prostate 1 (STEAP1). In addition, as announced earlier today, Xilio entered into a collaboration, license and option agreement with AbbVie leveraging Xilio's proprietary tumor-activation technology and platform to discover and develop novel tumor-activated immunotherapies, including masked T cell engagers. Under the collaboration, Xilio will receive $52.0 million in upfront payments and be eligible for additional option-related fees and milestones, as well as tiered royalties.

"Today, we are excited to announce the next phase of Xilio's tumor-activation platform with multiple internal masked T cell engager programs, as well as a multi-program collaboration with AbbVie," said René Russo, Pharm.D., president and chief executive officer of Xilio. "T cell engagers have demonstrated meaningful clinical activity, yet many promising targets for solid tumors remain out of reach due to toxicity limitations. Leveraging our clinically-validated masking technology, we aim to lead the next wave of innovation in cancer immunotherapy by developing masked T cell engagers designed to improve tolerability through tumor-selective activation. In addition, we are able to incorporate co-stimulatory signaling into our T cell engager designs with the goal of further enhancing T cell activation, persistence and anti-tumor activity. We look forward to collaborating with AbbVie as we advance our pipeline of novel tumor-activated immunotherapies."

Masked T Cell Engager Programs

T cell engagers are designed to redirect immune effector cells against cancer cells by simultaneously binding to a specific tumor-associated antigen expressed on the cancer cells and the T cell receptor complex on T cells, resulting in T cell-mediated killing of tumor cells. To date, T cell engagers have demonstrated significant promise as cancer immunotherapies in a variety of advanced solid tumors, but their potential has been limited by toxicity.

Xilio is leveraging its proprietary, clinically-validated tumor-activation platform to advance a pipeline of wholly-owned, novel masked T cell engager molecules with conditional half-life modulation designed to enable potent, localized T cell activation and tumor cell destruction together with an improved therapeutic index. These programs include bispecific molecules designed using Xilio's advanced tumor-activated cell engager (ATACR) format, which consists of a T cell engager with a masked CD3 targeting domain, and tri-specific molecules designed using Xilio's selective effector-enhanced cell engager (SEECR) format. The SEECR format builds upon the ATACR format by adding co-stimulatory signaling designed to further enhance potency and T cell activation.

Xilio is currently advancing three wholly-owned preclinical programs for masked T cell engager molecules targeting the following tumor-associated antigens: PSMA, CLDN18.2 and STEAP1.

- PSMA has demonstrated potential as a T cell engager target for prostate cancer. Xilio anticipates nominating a development candidate for its PSMA program in the ATACR format in the third quarter of 2025 and submitting an investigational new drug application (IND) in the first quarter of 2027.
- CLDN18.2 has broad potential as a T cell engager target for gastric, pancreatic, esophageal and lung cancers. Xilio anticipates nominating a development candidate for its CLDN18.2 program in the ATACR format in the fourth quarter of 2025 and submitting an IND in the second quarter of 2027.
- STEAP1 has broad potential as a T cell engager target for prostate, colorectal and lung cancers. Xilio anticipates nominating a development candidate for its STEAP1 program in the SEECR format in the first half of 2026 and submitting an IND in the second half of 2027.

Anticipated milestones beyond the first quarter of 2026 are subject to obtaining sufficient additional capital.

Collaboration, License and Option Agreement with AbbVie

Under the terms of the collaboration, license and option agreement announced earlier today with AbbVie:

- Xilio will receive $52.0 million in upfront payments, consisting of a cash payment of $42.0 million and an equity investment by AbbVie of $10.0 million in Xilio common stock at a premium.

- Xilio granted AbbVie (i) an exclusive option for an initial program to discover and develop masked cell engager molecules (and subject to the terms of the agreement, the right to initiate up to two additional masked cell engager programs) and (ii) an exclusive license for a program to discover and develop a masked antibody-based immunotherapy.

- Xilio will be eligible to receive up to approximately $2.1 billion in additional contingent payments, consisting of option-related fees and development, regulatory and sales-based milestones. Xilio is also eligible to receive tiered royalties ranging in the mid to high single digits on annual global net product sales for licensed products.

Financial Guidance

Based on its current operating plans, Xilio anticipates that its existing cash and cash equivalents, together with the upfront payments under the agreement with AbbVie, will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2026.

Investor Conference Call Information

Xilio will host a conference call and webcast today (Wednesday, February 12, 2025) at 8:30 am ET. Viewers can access the webcast by using this link. Listeners who require dial-in access should register here to receive a unique PIN and information to join the call. Listeners are encouraged to join at least 15 minutes prior to the scheduled start time. The webcast will also be accessible under “Events & Presentations” in the Investors & Media section of the Xilio Therapeutics website at https://ir.xiliotx.com. A replay of the webcast will be archived on the website for 30 days following the presentation.

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. 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 development timelines for the masked T cell engager programs; the receipt of future contingent payments from AbbVie; the potential benefits of any of Xilio’s current or future product candidates in any indication; the sufficiency of, and the period in which Xilio expects to have, cash to fund its operations and additional development milestones; the availability of additional capital to fund future development; 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 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 masked T cell engager programs; 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 collaboration or partnership agreements with Roche, Gilead and AbbVie. 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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