Gilead and Xilio Announce Exclusive License Agreement for Tumor-Activated IL-12 Program

March 28, 2024

-- Gilead Granted Exclusive License to Xilio's Tumor-Activated IL-12 Program, Including XTX301, a Clinical-Stage IL-12 Molecule with Potential to Treat a Broad Range of Cancers --

FOSTER CITY, Calif. and WALTHAM, Mass., March 28, 2024 (GLOBE NEWSWIRE) -- Gilead Sciences, Inc. (Nasdaq: GILD) and Xilio Therapeutics, Inc. (Nasdaq: XLO) today announced an exclusive license agreement to develop and commercialize Xilio's Phase 1 tumor-activated IL-12 program, XTX301.

Xilio Therapeutics is a clinical-stage biotechnology company discovering and developing tumor-activated immuno-oncology therapies. The company is using its proprietary tumor-activation 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. XTX301 is currently being evaluated in a Phase 1 dose escalation trial in patients with advanced solid tumors.

"Xilio's novel tumor-activation platform naturally complements Gilead's clinical development program in difficult-to-treat cancers and expands our focus in immuno-oncology," said Bill Grossman, MD, PhD, Senior Vice President, Oncology Clinical Development, Gilead Sciences. "We believe IL-12 has the potential to treat a broad range of tumor types and are excited to partner with Xilio to advance XTX301, a tumor-activated IL-12, as a monotherapy and a combination therapy across a variety of solid tumors."

"Gilead's confidence in our tumor-activated technology, combined with their deep expertise in developing and commercializing novel immuno-oncology products, will enable us to accelerate and expand the development of XTX301, our tumor-activated IL-12," said René Russo, Pharm.D., President and Chief Executive Officer of Xilio. "We look forward to collaborating with Gilead as we seek to deliver on the potential for XTX301 to provide a meaningful benefit for a range of tumor types, including immunologically cold tumors, while overcoming the severe toxicities historically associated with IL-12."

Terms of the Agreement

Under the terms of the agreement, Xilio granted Gilead an exclusive global license to develop and commercialize XTX301, Xilio's tumor-activated IL-12. 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 premium. Xilio will be eligible to receive up to $604.0 million in additional contingent payments, including additional equity investments by Gilead, a 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.

Xilio will be responsible for conducting clinical development of 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 a $75 million transition fee. 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.

Gilead does not exclude acquired IPR&D expenses from its non-GAAP financial measures. This transaction is expected to reduce Gilead's GAAP and non-GAAP 2024 EPS by approximately $0.03 – $0.04.

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 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.).

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, COVID-19, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City,

California.

Xilio Therapeutics 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 amount of proceeds expected from the transactions with Gilead; the timing and certainty of completion of the transactions with Gilead; the potential benefits of any of Xilio's current or future product candidates in treating patients as a monotherapy or combination therapy; the potential for Xilio to leverage its research platform to develop bispecific or cell engager molecules; 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, general market conditions; whether the conditions for the closing of the transactions with Gilead will be satisfied; 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 and collaboration 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.

Gilead Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including Gilead's ability to realize the anticipated benefits from the collaboration with Xilio; difficulties or unanticipated expenses in connection with the collaboration, and the potential effects on Gilead's earnings; the risk that Gilead's investment in Xilio will lose value for any number of reasons; the ability of the parties to initiate, progress or complete clinical trials within currently anticipated timelines or at all, and the possibility of unfavorable results from trials, including those involving XTX301, and additional programs that may become subject of the collaboration; the ability of the parties to file applications for regulatory approval or receive regulatory approvals in a timely manner or at all for the investigational programs developed pursuant to the collaborations, and the risk that any such approvals may be subject to significant limitations on use; the possibility that the parties may make a strategic decision to terminate the collaboration or discontinue development of any of the investigational programs subject to the collaboration, and therefore these investigational programs may never be successfully commercialized; and any assumptions underlying any of the foregoing. These and other risks, uncertainties and other factors are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.

For more information about Gilead, please visit the company's website at www.gilead.com, follow Gilead on X/Twitter (@Gilead Sciences) and LinkedIn (@Gilead-Sciences).

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