Xilio Therapeutics Announces Initiation of Patient Dosing in Phase 1/2 Clinical Trial of XTX202 for the Treatment of Patients with Solid Tumors

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WALTHAM, Mass., Jan. 20, 2022 (GLOBE NEWSWIRE) -- Xilio Therapeutics, Inc. (Nasdaq: XLO), a biotechnology company developing tumor-selective immuno-oncology therapies for people living with cancer, today announced that the first patient has been dosed in the company's Phase 1/2 clinical trial evaluating XTX202 for the treatment of solid tumors. XTX202 is a modified form of IL-2 that is designed to localize activity in the tumor microenvironment (TME), with the goal of overcoming the known tolerability challenges of existing IL-2 therapies while achieving enhanced anti-tumor activity.

"We are pleased to begin patient dosing in our Phase 1/2 clinical trial with XTX202, a novel tumor selective IL-2 candidate with the potential to increase the therapeutic benefit of IL-2," said Marty Huber, M.D., president of research and development and chief medical officer of Xilio Therapeutics. "XTX202 has been designed to be active only within the TME, with the goal of reducing dose limiting toxicity and enhancing anti-tumor activity. We look forward to advancing this trial to further our understanding of XTX202 as a potential therapy for the treatment of people living with cancer."

Leveraging its proprietary geographically precise solutions (GPS) platform, Xilio designed XTX202 to be masked with a protein domain to prevent binding activity until the protein domain is cleaved off by TME-associated proteases. XTX202 is intended to be activated selectively in the TME, resulting in localized anti-tumor activity without dose-limiting toxicities. In preclinical studies, XTX202 exhibited tumor-selective biological activity and anti-tumor activity comparable to aldesleukin, a high-dose IL-2 therapy, at its maximum tolerated dose, while minimizing the severe toxicity observed with aldesleukin. In non-human primate models, XTX202 was well-tolerated at doses up to 10 mg/kg weekly.

The Phase 1/2 clinical trial is a first-in-human, multi-center, open-label trial that will evaluate XTX202 as a monotherapy in patients with advanced solid tumors. The Phase 1 portion of the trial consists of a dose-escalation monotherapy cohort designed to evaluate the safety and tolerability of XTX202 and determine the recommended Phase 2 dose. Following completion of the Phase 1 portion, Xilio plans to initiate Phase 2 expansion cohorts with XTX202 monotherapy evaluating the objective response rate in patients with renal cell carcinoma or melanoma who previously received an anti-PD-1 treatment regimen. Xilio also plans to initiate one or more additional Phase 1 trials aimed at demonstrating utility of XTX202 in combinations with other agents such as anti-PD-1 agents or tyrosine kinase inhibitors. More information on the trial can be found at https://clinicaltrials.gov (NCT05052268).

About Xilio Therapeutics
Xilio Therapeutics is a clinical-stage biotechnology company focused on harnessing the immune system to achieve deep and durable clinical responses to improve the lives of people living with cancer. The company is using its proprietary geographically precise solutions (GPS) platform to rapidly engineer novel molecules, including cytokines and other biologics, that are designed to optimize their therapeutic index. These molecules are designed to localize activity within the tumor microenvironment without systemic effect, resulting in the potential to achieve enhanced anti-tumor activity. Xilio is building a pipeline of wholly owned, tumor-selective, GPS-enabled cytokine and checkpoint inhibitor product candidates, including XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody; XTX202, a tumor-selective IL-2; XTX301, a tumor-selective IL-12; and XTX401, a tumor-selective IL-15. For more information, please visit www.xiliotx.com.

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 initiate Phase 2 expansion cohorts with XTX202 monotherapy; plans to initiate one or more additional Phase 1 trials aimed at demonstrating utility of XTX202 in combinations with other agents; plans, strategies, timelines and expectations for Xilio's current or future approved product candidates; plans and timing related to initial data for Xilio's product candidates; the potential benefits of any of Xilio's current or future product candidates in treating patients, including the ability of XTX202 to increase the therapeutic benefit of IL-2; 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," "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; preclinical and clinical supply of current or future product candidates; Xilio's advancement of multiple early-stage programs; 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 current or future operating expenses and capital expenditure requirements; and the impact of the COVID-19 pandemic on Xilio's business, operations, strategy, goals and anticipated milestones. 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.

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