Xilio Therapeutics Announces Initiation of Patient Dosing in Phase 1/2 Clinical Trial of XTX101 for the Treatment of Patients with Solid Tumors

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WALTHAM, Mass.--(BUSINESS WIRE)--Xilio Therapeutics, Inc. (Xilio) a biotechnology company developing tumor-selective immuno-oncology therapies for patients with cancer, today announced that the first patient has been dosed in the company's Phase 1/2 clinical trial evaluating XTX101 for the treatment of solid tumors. XTX101 is a tumor-selective anti-CTLA-4 monoclonal antibody designed to improve upon the therapeutic index of existing anti-CTLA-4 therapies by overcoming their historical potency and tolerability limitations.

"The initiation of our first clinical trial with XTX101 is an exciting moment for Xilio and for the patients with cancer who we believe would benefit from anti-CTLA-4 therapies, but are limited because of toxicity challenges," said Marty Huber, M.D., chief medical officer of Xilio Therapeutics. "In preclinical studies, XTX101 has shown potential to deliver meaningful responses and favorable tolerability. Our Phase 1/2 clinical trial will evaluate XTX101 as a monotherapy as well as in combination with the checkpoint inhibitor pembrolizumab. We look forward to advancing this trial and exploring the therapeutic potential of XTX101 for patients."

Leveraging its proprietary geographically precise solutions (GPS) platform, Xilio engineered XTX101 to be activated in the tumor microenvironment with the potential to result in localized clinical activity without dose-limiting toxicities. In preclinical studies, XTX101 exhibited tumor-selective biological activity and robust tumor growth inhibition, including complete responses in murine cancer models, with favorable tolerability. These data demonstrate enhanced activity and an improved tolerability profile compared to an analog of ipilimumab, a CTLA-4 blocking antibody approved for the treatment of certain solid tumor cancers. XTX101 has also demonstrated enhanced tumor growth inhibition and tolerability when administered in combination with an anti-PD-1 *in vivo*.

The Phase 1/2 clinical trial is a first-in-human, multi-center, open-label trial that will evaluate the safety and tolerability of XTX101 as a monotherapy, as well as a combination therapy with pembrolizumab, for the treatment of adult patients with advanced solid tumors. The Phase 1 portion of the trial will consist of three cohorts, beginning with an accelerated and standard 3+3 dose-escalation monotherapy cohort to assess the tolerability of XTX101 at the target dose in patients with advanced solid tumors who have progressed after receiving the standard-of-care treatment for their tumor. Following completion of enrollment in the dose-escalation cohort, XTX101 will be evaluated in a monotherapy cohort designed to evaluate evidence of anti-CTLA-4 pharmacodynamic activity in patients who have progressed on anti-PD-1 or anti-PD-L1 treatment but have not received prior treatment with an anti-CTLA-4 therapy, and XTX101 will be evaluated in combination with pembrolizumab in patients who have not previously been treated with an anti-PD-1 or anti-PD-L1 treatment. The Phase 1 portion of the trial is anticipated to enroll approximately 100 patients across all cohorts at multiple sites in the United States.

About Xilio Therapeutics

Xilio Therapeutics is a privately-held biotechnology company focused on harnessing the immune system to achieve deep and durable clinical responses to improve the lives of patients 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.

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