Xilio Therapeutics Announces Clinical Trial Collaboration With Merck on Anti-CTLA-4 Monoclonal Antibody Program

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Xilio to evaluate XTX101, a tumor selective anti-CTLA-4 monoclonal antibody, in combination with KEYTRUDA® (pembrolizumab) as a treatment for patients with solid tumors

WALTHAM, Mass., May 25, 2021 (BUSINESS WIRE) -- Xilio Therapeutics, a biotechnology company developing tumor-selective immuno-oncology therapies for patients with cancer, announced today that it has entered into a clinical trial collaboration and supply agreement with Merck, known as MSD outside the United States and Canada, to evaluate XTX101, Xilio's engineered tumor-selective Fc-enhanced, anti-CTLA-4 monoclonal antibody (mAb) product candidate, in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy. The planned clinical trial will be conducted by Xilio and is designed to evaluate the safety and efficacy of XTX101 as a monotherapy and in combination with KEYTRUDA in patients with solid tumors.

"We believe tumor-selective immuno-oncology has significant potential to provide meaningful treatments to patients with a number of different cancers. The clinical benefit of targeting CTLA-4 as a treatment for cancer is well-established. However, treatment with the combination of an anti- CTLA-4 mAb and PD-1 checkpoint inhibitor has been associated with challenging toxicities, preventing patients from receiving effective doses of the anti-CTLA-4 antibody," said Marty Huber, M.D., chief medical officer of Xilio Therapeutics. "XTX101 is designed to be tumor-selective and based on data observed in preclinical studies, we believe it could be an ideal CTLA-4-targeting candidate to combine with checkpoint inhibitors like KEYTRUDA. We are pleased to partner with Merck to study this combination in an effort to improve therapeutic options for people with cancer."

XTX101 is a tumor-selective anti-CTLA-4 mAb designed to pinpoint the anti-CTLA-4 effect geographically within the tumor without off-tumor peripheral effects, potentially improving the therapeutic index and overcoming the potency and tolerability limitations of other anti-CTLA-4 antibodies. In preclinical studies, XTX101 has been well-tolerated and achieved robust tumor growth inhibition, including complete responses accompanied by tumor-selective immune activation. Xilio plans to submit an investigational new drug (IND) application for XTX101 to the U.S. Food and Drug Administration (FDA) in the second quarter of 2021. Subject to FDA clearance of the IND application, Xilio expects to promptly initiate a Phase 1 clinical trial evaluating XTX101 as a monotherapy and as a combination therapy with KEYTRUDA for the treatment of solid tumors.

About Xilio Therapeutics

Xilio Therapeutics is a privately-held biotechnology company that uses its proprietary technology to engineer potent cancer immunotherapies that have the potential to unleash the power of the immune system selectively at the site of the tumor. Xilio has designed its investigational therapies with the goal of maximizing efficacy and overcoming the serious toxicities associated with certain clinically validated immuno-oncology therapies, positioning them as potential treatments for a significant number of patients. The company's proprietary pipeline includes XTX202, a tumor- selective modified form of IL-2, and XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody (mAb), as well as tumor-selective IL-12 and IL-15 research programs. Xilio was founded in 2016 and is headquartered in Waltham, Mass. For more information, please visit www.xiliotx.com.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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