Xilio Therapeutics Announces FDA Acceptance of IND Application for XTX101 for the Treatment of Solid Tumors

WALTHAM, Mass., June 17, 2021 – Xilio Therapeutics, a biotechnology company developing tumor-selective immuno-oncology therapies for patients with cancer, today announced that the U.S. Food and Drug Administration has accepted its Investigational New Drug application (IND) to evaluate its checkpoint inhibitor product candidate, XTX101, as a potential treatment for patients with 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.

"This first IND acceptance for Xilio represents a significant milestone for us as we transition to a clinical-stage organization," said Marty Huber, M.D., chief medical officer of Xilio Therapeutics. "It is well known that checkpoint inhibitors hold significant clinical potential; however, treatment with anti-CTLA-4 therapies has been limited because of challenging autoimmune toxicities. Using our geographically precise solutions (GPS) platform, we have engineered XTX101 with the goal of enhancing the desirable features of an anti-CTLA-4 antibody while limiting the known liabilities. We look forward to beginning Phase 1 development to evaluate the potential that XTX101 may offer as both a monotherapy and combination agent for patients in need."

Leveraging its proprietary GPS platform, Xilio designed 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*.

Xilio expects to initiate a Phase 1 clinical trial in the second half of 2021 to evaluate XTX101 as a monotherapy, as well as a combination therapy with KEYTRUDA® (pembrolizumab), for the treatment of patients with solid tumors.

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 programs, including XTX202, a tumor-selective IL-2 product candidate; XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody; and tumor-selective IL-12 and IL-15 research programs. For more information, please visit www.xiliotx.com.

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