Xilio Therapeutics Announces FDA Clearance of Investigational New Drug Application for XTX202 for the Treatment of 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 U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application to evaluate XTX202, its tumor-selective IL-2 product candidate, as a potential treatment for patients with solid tumors. XTX202 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 excited to have received FDA clearance for our IND application for XTX202,” said Martin Huber, M.D., president of research and development and chief medical officer of Xilio. “IL-2 has shown potential for long-term, durable complete responses in certain cancers, but life-threatening toxicity has limited its use to a small subset of patients. We have designed XTX202 with the goal of delivering enhanced anti-tumor activity while minimizing the known liabilities of existing IL-2 therapies. We look forward to beginning Phase 1/2 development to evaluate the potential that XTX202 may offer as both a monotherapy and combination agent for patients in need.”

Leveraging its proprietary geographically precise solutions (GPS) platform, Xilio designed XTX202 to be activated selectively in the TME, resulting in localized clinical 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. XTX202 was well-tolerated in non-human primate models up to 10 mg/kg weekly.

Xilio expects to initiate a Phase 1/2 dose-escalation monotherapy trial for XTX202 in patients with solid tumors who have previously received an anti-PD(L)1 treatment regimen in the first quarter of 2022.

About Xilio Therapeutics

Xilio Therapeutics is a 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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