Ankyra Therapeutics Receives FDA IND and Health Canada CTA Approval to Advance First-In-Class Selective Anchored Immunotherapy Agent, ANK-101, into Human Trials in Solid Tumors

Clearance from U.S. Food & Drug Administration and Health Canada permits Phase I open-label dose escalation study to begin in first quarter of 2024

IL-12- based anchored immunotherapy increases immune cell infiltration into tumors while decreasing systemic toxicity in preclinical models

CAMBRIDGE, MA – October 24, 2023 (BUSINESSWIRE) – Ankyra Therapeutics, a clinical stage biotechnology company pioneering anchored immunotherapies to treat cancer, today announced approval of its investigational new drug (IND) application by the U.S. Food & Drug Administration (FDA) and clinical trial application (CTA) by Health Canada for its lead agent, ANK-101, a novel tumor-directed anchored immune medicine. The Company plans to initiate a first-in-human Phase I clinical trial of ANK-101 as a single agent in early 2024 at a limited number of clinical sites in the U.S. and Canada in patients with advanced solid tumors who have failed standard of care treatments.

ANK-101, an interleukin-12 (IL-12) cytokine anchored to aluminum hydroxide, is locally delivered and retained in the tumor microenvironment for several weeks where it mediates recruitment and activation of effector immune cells. Ankyra has demonstrated single agent activity of ANK-101 in preclinical studies of various solid tumors in mice as well as in canine melanoma (cANK-101) with a tolerable safety profile.

“By anchoring to and being retained at the tumor site, ANK-101 has the ability to avoid hallmark challenges of both systemic and intratumoral therapies, namely by preventing cytokine diffusion, effectively training the body to potently destroy cancer cells,” said Howard L. Kaufman, MD, CEO and President of Ankyra Therapeutics. “We are very excited about the clearance of our CTA and IND, which will allow us to bring ANK-101 to patients who may benefit from this new approach to cancer treatment.”

Joe Elassal, MD, MBA, Ankyra’s Chief Medical Officer, added “ANK-101 represents potential treatment benefit without unwanted side effects. Our hope is that by anchoring the IL-12 at the site of tumor growth, we will see therapeutic activity without systemic toxicity. We look forward to advancing our first-in-class asset to realize this vision, and to paving the way for anchored immunotherapy to safely deliver other biologically active agents in the future.”

About ANK-101

ANK-101 is an anchored drug complex composed of interleukin-12 (IL-12) linked to aluminum hydroxide. ANK-101 enables local delivery of functional IL-12 to the tumor microenvironment where it remains biologically active for several weeks but does not diffuse into the systemic

circulation, thereby avoiding systemic toxicity. Treatment with ANK-101 in animal models has been associated with recruitment and retention of tumor-specific CD8+ T cells, NK cells and M1 macrophages activating innate and adaptive anti-tumor immunity. ANK-101 is being evaluated for the treatment of advanced solid tumors alone and in combination with anti-PD-1 agents.

About Ankyra Therapeutics

Ankyra Therapeutics is a biotechnology company pioneering anchored immunotherapies to transform cancer treatment. The company's platform is fueling a pipeline of novel therapeutics, including cytokine therapies, designed to anchor to the tumor microenvironment for sustained local delivery and retention at higher concentrations, while minimizing systemic exposure and on-target/off-tumor effects. The company's lead program ANK-101, IL-12 anchored to aluminum hydroxide with potential to treat a broad range of cancers, will enter the clinic in 2024. For more information, please visit www.ankyratx.com

For Investor Inquiries:
Howard L. Kaufman, MD
President and CEO
Ankyra Therapeutics
info@ankyratx.com

For Media Inquiries:
Joan Bosisio
Verge Scientific Communications
joan.bosisio@vergescientific.com