



Ankyra Therapeutics Announces First Visceral Tumor Patient Dosed in Phase 1 ANCHOR Clinical Trial of ANK-101, an Anchored Interleukin-12 (IL-12)

Safety and tolerability to be determined at up to 5 study sites in the United States and Canada

November 5, 2024 (Cambridge, MA) – Ankyra Therapeutics, a clinical stage biotechnology company pioneering anchored therapy to treat cancer, today announced the first patient dosed in a visceral tumor in Part 2 of their dose escalation Phase 1 study. The ANCHOR study is a first-in-human Phase 1 study being conducted in two parts. Part 1 is enrolling patients with superficially accessible tumors and is expected to complete enrollment by December 2024. Part 2 is now open to patients with solid tumors located in deep viscera accessed by interventional radiologic or endoscopic procedures for injection.

Referred to as “anchored therapy” the company has identified a method for prolonged drug retention within the tumor microenvironment. The anchored strategy drives local anti-tumor activity, similar to antibody drug conjugates, while limiting systemic toxicity. The company’s lead asset, ANK-101, is an interleukin-12 (IL-12) physically anchored to aluminum hydroxide. ANK-101 is locally delivered and retained in the tumor microenvironment for several weeks where it mediates recruitment and activation of effector immune cells. In multiple preclinical models, a murine adapted ANK-101 demonstrated increased immune cell infiltration and activation with significant therapeutic activity across multiple tumor types. In addition, a canine version of ANK-101 has been evaluated in an exploratory phase I study in dogs with advanced melanoma. Human ANK-101 is now in Phase 1 clinical trials for solid tumors in the U.S. and Canada.

“The first patient dosed in the Part 2 of our Phase 1 study advances our lead asset into visceral solid tumors and marks a key milestone in our mission to bring novel medicines to patients with cancer” said Joe Elassal, M.D. MBA. Part 2 of the ANCHOR study will assess the safety of ANK-101 and determine the recommended dose for expansion in patients with viscerally injected solid tumors. Secondary objectives include evaluation of pharmacokinetics, immunogenicity, and preliminary clinical activity of the medicine. Enrollment in Part 1 of the ANCHOR trial is ongoing.

“I have been impressed with ANK-101 in Part 1 of the Phase 1 study and expansion of the trial to include visceral lesions will enable us to deliver ANK-101 to a broader group of cancer patients” said Jong Chul Park, MD, Assistant Professor at Harvard Medical School and attending physician at Mass General Cancer Center. He added “we look forward to advancing this part of the trial and exploring the safety and therapeutic potential of ANK-101 for patients with more advanced disease.”



About ANK-101

ANK-101 is an anchored drug complex composed of human 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 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. Phase 1 first-in-human, open-label clinical trial of ANK-101 as a monotherapy (NCT:06171750) consists of dose escalation portions in both superficial and visceral lesions that will evaluate the safety and tolerability of ANK-101, followed by dose expansion cohorts.

About Ankyra Therapeutics

Ankyra Therapeutics is a biotechnology company pioneering anchored therapy 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. Ankyra's lead program ANK-101, IL-12 anchored to aluminum hydroxide, has potential to treat a broad range of cancers. For more information, please visit www.ankyratx.com.

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