Ankyra Therapeutics Announces Trial in Progress Poster Presentation at 2024 ASCO Meeting and Approval of ANK-101 Phase 1 Protocol Amendment

Ankyra Therapeutics will provide an update on the status of the ANK-101 Phase 1 ANCHOR clinical trial at ASCO 2024 and has received approval by FDA and Health Canada to amend the Phase I study to include patients with solid tumors in visceral organs

June 1, 2024 (Cambridge, MA) – Ankyra Therapeutics, a clinical-stage oncology company developing anchored immunotherapies to improve the therapeutic window for immuno-oncology drugs, announced today that it is presenting a Trial in Progress poster for the phase 1 ANCHOR clinical trial at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting being held May 31 – June 4, 2024 in Chicago, IL.

Ankyra Therapeutics has developed an anchored drug-delivery platform based on linking immunotherapy drugs to aluminum hydroxide. The linked compounds are delivered locally to the tumor, where they are retained for several weeks promoting anti-tumor activity without systemic toxicity. Ankyra's lead asset, ANK-101, is comprised of interleukin-12 with an alum-binding peptide that enables direct linkage with aluminum hydroxide. The ANCHOR study is a multi-institution, first-in-human, phase I clinical trial of ANK-101 in patients with superficially accessible solid tumors who have progressed after standard therapy was initiated in February 2024. The primary objectives of the study are to determine the safety, tolerability, and recommended dose of ANK-101 for further studies. The trial is active at five clinical study sites: Massachusetts General Hospital in Boston, MA; Providence Cancer Institute in Portland, OR; University of Pittsburgh in Pittsburgh, PA; Princess Margaret Hospital in Toronto, ON; and the National Cancer Institute (NCI), part of the National Institutes of Health, in Bethesda, MD. The poster presentation will include the rationale for the trial, study objectives, clinical trial design, and an update on accrual. The study will also evaluate pharmacokinetics, immune biomarkers, and quality of life.

In addition, Ankyra has received clearance from both the U.S. Food and Drug Administration (FDA) and Health Canada to amend the phase I clinical trial to include a second dose-escalation and expansion part to evaluate ANK-101 for injection into solid tumors located in visceral organs. This part will run concurrently with the current Phase I study with dosing to begin once patients in the superficial part have cleared a 21-day dose-limiting toxicity (DLT) observation period.

"We are delighted with the progress in the current phase I study which will help establish the initial safety profile and dosing selection for ANK-101," stated Howard L. Kaufman, MD, CEO of Ankyra Therapeutics. Dr. Kaufman also stated that "this study is the first step to realize the potential for anchored immunotherapy to deliver high doses of immunotherapy without systemic toxicity, which could represent an important advance in how we deliver effective cancer treatment in a safer manner." Joe Elassal, MD, Chief Medical Officer at Ankyra added "the recent approval to extend ANK-101 to visceral tumors is especially exciting as we can now study a broader patient population that could extend the potential indications for ANK-101 treatment".

For patients interested in enrolling in this clinical trial at NCI, please call NCI's toll-free number: 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615); visit the website: https://trials.cancer.gov; and/or email: NCIMO_referrals@mail.nih.gov.

Title: A phase 1, open-label, dose escalation study on the safety and tolerability of ANK-101 in advanced solid tumors
Session Type: Poster Session
Session Title: Developmental Therapeutics – Immunotherapy
Track: Developmental Therapeutics – Immunotherapy
Sub Track: New Targets and New Technologies (IO)
Session Date and Time: Saturday June 1, 2024 9:00 AM CDT
Location: Hall A
Poster Board Number: 158a
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The poster will be available on the publications section of Ankyra's website after the meeting at https://ankyratx.com/#science.

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 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. The Phase 1 first-in-human, open-label clinical trial of ANK-101 as a monotherapy (NCT:06171750) consists of a dose escalation portion that will evaluate the safety and tolerability of ANK-101, followed by dose expansion cohorts.

About Ankyra Therapeutics
Ankyra Therapeutics is a biotechnology company that has developed a highly differentiated technology platform that expands the therapeutic window of cytokine drugs by forming a stable depot in the tumor after local administration leading to prolonged immune activation and potent local and systemic immunity with reduced systemic toxicity. Ankyra was founded in 2019 and is headquartered in Cambridge, Massachusetts. For more information, please visit www.ankyratx.com

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